



SOUTHERN AFRICAN DEVELOPMENT COMMUNITY RESEARCH ETHICS GUIDELINES

Prepared by the Northern Regions Community of Practice for Ethics and Integrity in Southern Africa in collaboration with the Southern African Research Innovation and Management Association and Management Association and Southern Africa Network for Biosciences (SANBio)

NOVEMBER 8, 2021

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ACKNOWLEDGEMENTS

The Southern African Research and Innovation Management Association (SARIMA) is strategically promoting the implementation of a Regional Research Ethics Guideline and Toolkit that can be used by individual researchers, research institutions, and governments of Southern African Development Community (SADC) member states as a standard approach to applying moral, ethical, and professional codes.

SARIMA appreciatively acknowledges the contributions of the members of the Northern Region Community of Practice for Research Ethics and Integrity in Southern Africa for developing the Guideline and Toolkit, informed by a desktop literature review and a review of relevant source material. We want to thank Eleni Flack-Davison and Sidney Engelbrecht for leading the project with professionalism and ensuring the timely delivery of a high-quality result. The Working Group members were actively involved in critical discussions to frame the product. Jasper Knight, with the assistance of Postgraduate students from the University of the Witwatersrand, Johannesburg, played a pivotal role in authoring the desktop literature review on the implementation of the Nagoya Protocol across the Southern African Development Community (SADC). Jasper also merits praise for his thorough critical reading of the product's many components and editorial assistance. Special thanks go to Retha Visagie and Winston Beukes who led the work of the sub-groups working on the Guideline and the Toolkit documents and conceptualised these two documents. Tanya Coetzee played a vital role in the project, and we wish to thank her. She served as the secretariat and interface for the working groups, ensuring that they ran well. Tanya Coetzee, Eleni Flack-Davison, Sidney Engelbrecht and Winston Beukes made substantial contributions to both the Guideline and Toolkit working groups, whereas Marizvikuru Manjoro, Dimpho Ralefala, Retha Visagie and Pamela Claassen focused their attention on various sections of the Guideline. We thank the external reviewers of these documents undertaken through SARIMA: Prof Sechaba Bareetseng, Dr Prenitha Sewnarain, Dr Jacintha Toohey, and Malené Fouché. Sechaba and Prenitha played a critical role in initiating and conceptualising this project. We also wish to acknowledge the contribution of Leatitia Romero in providing the final touches to the product to ensure quality formatted and technically correct documents.

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GLOSSARY OF TERMS

This short Glossary of Terms contains a combination of commonly used acronyms, terms and definitions. Please note that in certain places of the Literature Review, SADC Research Ethics Guideline and Toolkit, specific or particularly relevant terms to that document are defined.

“ABS”	Access and Benefit Sharing
“ABSCH”	Access and Benefit-Sharing Clearing-House
“ALLEA”	All European Academies
“AREC”	Animal Research Ethics Committee
“ARIPO”	African Regional Intellectual Property Organization
“AU”	African Union
“BMZ”	German Federal Ministry for Economic Cooperation and Development
“BREC”	Biosafety Research Ethics Committee
“BRICS”	Brazil, Russia, India, China, South Africa
“CBD”	United Nations Convention on Biological Diversity
“COMIFAC”	Central Africa Forest Commission
“EU”	European Union
“FAO”	Food and Agriculture Organization
“FFP”	Fabrication, Falsification and Plagiarism
“GIZ”	Deutsche Gesellschaft für Internationale Zusammenarbeit
“HRDC”	Health Research and Development Committee
“HREC”	Human Research Ethics Committee
“IK”	Indigenous Knowledge
“IKS”	Indigenous Communities and Knowledge Systems
“INBAC”	National Institute for Biodiversity and Protected Areas
“INRs”	Interim National Reports
“IRB”	Institutional Review Board
“IP”	Intellectual Property
“IPRs”	Intellectual Property Rights
“ITPGRFA”	International Treaty on Plant Genetic Resources for Food and Agriculture
“IWGIA”	International Work Group for Indigenous Affairs

“MOU”	Memoranda of Understanding
“MAT”	Mutually Agreed Terms
“NCP”	National Contact Point
“NP”	Nagoya Protocol
“PGRFA”	Plant Genetic Resources for Food and Agriculture
“PIC”	Prior Informed Consent
“R&I”	Research and Innovation
“RE”	Regional Research Ethics
“REC”	Research Ethics Committee
“RIO”	Research Integrity Office
“SADC”	Southern African Development Community
“SARIMA”	Southern African Research and Innovation Management Association
“SANBio”	Council for Scientific and Industrial Research
“SDGs”	Sustainable Development Goals
“SMTA”	Standard Material Transfer Agreement
“STI”	SADC Secretariat on Science, Technology and Innovation
“3Rs”	Replacement, Reduction and Refinement

As indicated in Table 1, unless the context indicates otherwise, the following terms will bear the following meanings:

Table 1: Glossary of Terms

TERM	DEFINITION
Autonomy	A person/participant's right to self-determination, free from influences from others by virtue of the person's inherent dignity;
“Access and Benefit Sharing” / “ABS”	Is an established international system that spells out the way in which genetic resources and associated traditional knowledge (TK) are accessed, and how the benefits that result from their use are shared between the users and the providers. The concept of access and benefit sharing was coined during negotiations and signing of Convention on Biological Diversity (CBD) in 1992. In its third objective, CBD requires all contracting parties to ensure fair and equitable access to genetic resources and sharing of benefits

TERM	DEFINITION
	accruing from utilization of genetic resources and associated TK (Greiber et al., 2012); ¹
“Biodiversity” / “Biological Diversity”	Means the variability among living organisms from all sources including, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part and also includes diversity within species, between species, and of ecosystems; ²
“Bioprospecting”	In relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes-(a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application; (b) the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; or (c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation; ³
“Collective autonomy”	Pertains to a social group's interdependent state of being characterized by the group's ability to make collaborative decisions based on shared beliefs;
“FAIR Principles”	Findable, Accessible, Interoperable and Reusable
“Indigenous Biological Resources”	(a) When used in relation to bioprospecting, means any indigenous biological resource as defined in section 80(2); or (b) when used in relation to any other matter, means any resource consisting Of- (i) any living or dead animal, plant or other organism of an indigenous species; (ii) any derivative of such animal, plant or other organism; or (iii) any genetic material of such animal, plant or other organism; ⁴
“Traditional Knowledge”	Means subject to its national legislation, “any knowledge originating from a local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, where the knowledge is embodied in the traditional lifestyle of a community,

¹ Kenya’s Access and Benefit Sharing Toolkit for Genetic Resources and Associated Traditional Knowledge - NEMA/National Environment Management Authority 2014

² National Environmental Management: Biodiversity Act No. 10 of 2004

³ National Environmental Management: Biodiversity Act No. 10 of 2004

⁴ National Environmental Management: Biodiversity Act No. 10 of 2004

TERM	DEFINITION
	or contained in the codified knowledge systems passed on from one generation to another. ⁵ The phrase does not refer to a single technical discipline; it can refer to agricultural, environmental, or medicinal knowledge, as well as genetic resource knowledge.
“Intellectual Property”	Mean any creation of the mind that is capable of being protected by law from use by any other person and includes any rights in such creation, any and/or all technical and/or commercial information, chemical structures, biological and/or chemical information, manufacturing techniques and/or designs, specifications and/or formulae, know-how, data, systems and/or processes, production methods, methodologies, trade secrets, undisclosed inventions, financial and/or marketing information, as well as registered and/or unregistered intellectual property in the form of patents and/or inventions, trademarks, designs and/or plant breeders’ registrations and/or varieties (whether granted, registered and/or applied for), and/or copyright in any works including, but not limited to, literary works and/or computer software programs; ⁶
“Nagoya Protocol” / “NP”	Means Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity;
“Research Participant”	Someone with an active role participating in research using direct interaction, whereas research subject includes persons (or animals) involved in research without giving explicit consent to participate (Weinbaum et al., 2019).

1. INTRODUCTION

This Guideline aims to harmonise research ethics and integrity in the Southern African Development Community (SADC), first through the lenses of accepted codes of conduct and, second, the Nagoya Protocol. Resource constraints and a lack of political will in some countries in the SADC region call for initiatives to improve research ethics governance systems directed by consensus. Where governance systems exist, the principles, standards and practices guiding responsible and ethical research are

⁵ Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore. Available at: <https://www.aripo.org/wp-content/uploads/2019/06/Swakopmund-Protocol-on-the-Protection-of-Traditional-Knowledge-and-Expressions-of-Folklore-2019.pdf>

⁶ African Regional Intellectual Property Organization (ARIPO) (2019). Available at <https://www.aripo.org/wp-content/uploads/2019/11/ARIPO-Guidelines-for-Ratification-or-Accession-and-Domestication-of-International-Instruments-on-Copyright-and-Related-Rights.pdf>

influenced by biomedical research ethics codes emanating mainly from the Global North. Key ethical codes used internationally include but are not limited to the Belmont Report (1979), Declaration of Helsinki adopted by the World Medical Association (1964, last revised in 2018), the Council for International Organizations of Medical Sciences (CIOMS) (1982, last revised in 2016), and the 'Common Rule' (CFR 46) adopted by US Federal departments and some African countries. It is noteworthy that a consensus CIOMS working group recently released a guideline for 'Clinical research in resource-limiting settings.'⁷ This report aims to promote good quality clinical research in lower and middle income countries. Despite all these efforts, there remains a need to develop a generic set of guidelines that can be applied across SADC to diverse types of research. The spirit of this Guideline is to fill this gap. This intention resonates with Agenda 2063, some Sustainable Development Goals (SDGs), and the region's sustainable capacity development initiative to impact society and promote Science, Technology and Innovation. Member States should take note that Country sovereignty rights must remain at the fore of all adoption, development and implementation of the Guideline and Toolkit in their own resources.

A desktop literature review and integrated analysis of the comparison of responses across different countries on the implementation of the Nagoya Protocol through existing or new legislation, or strategies, shows significant limitations in the SADC nations' capabilities for adopting and implementing the protocol (see Appendix A, Table 1). Commonly cited reasons for these constraints include a lack of clarity on which national agency should take responsibility, specifically where multiple agencies are involved in managing genetic data, lack of capacity, lack of a supportive legislative context, a poorly coordinated overarching regulatory framework, lack of funding, inadequate human and financial resources, and a lack of qualified personnel. These constraints subsequently influence the type and quality of research conducted, policies and frameworks that guide research, and ultimately the quality of responsible and ethical research. It is, therefore, crucial for institutions, researchers, governments and other relevant stakeholders to devise strategies for resolving these limitations.

The outcome of the desktop literature review has provided a context for the development of the SADC Research Ethics Guideline and Toolkit. It further provides recommendations for future research and stakeholder engagement on different discipline-specific topics, thus, sharing best practices for compliance with the Nagoya Protocol.

⁷ Council for International Organizations of Medical Sciences (2021). Clinical Research in Resource-limiting settings. Available from: https://cioms.ch/wp-content/uploads/2021/06/CIOMS_ClinicalResearch_RLS.pdf

The Guideline and Toolkit serves the SADC research community in its entirety and is crucial for self-regulation concerning professional, ethical and legal responsibilities. There may also be constraints in the implementation of the guidelines. Still, the research community is urged to strive to abide by the essential research ethics principles provided, define the criteria for appropriate research behaviour in dealing with research participants, communities, and animals, maximise the quality and robustness of research, and respond adequately to threats to, or violations of, research integrity.

The interpretation of the principles and standards that regulate research may be affected by social, economic, cultural and political contexts, technological developments, and changes in the research environment. While different disciplines may use different approaches, they each share the motivation to deepen understanding of research concepts, discover issues and solve complex developmental or societal challenges. Consequently, research institutions must be alert and adjust to the research ethics and integrity codes based on the dynamism of the contextual environment to uphold the good conduct of research. An effective Guideline and Toolkit for the SADC research community must be a living document that should be updated regularly, allowing for local or national differences in its implementation. Researchers, academics, learned societies, governments, funding agencies, public and private research performing organisations, publishers and other relevant bodies each have specific responsibilities to observe and promote these principles and the practices that underpin them.

1.1 Framework to promote responsible and ethical research

The legacy of colonialism, unequal access to health systems and power relationships between government, donor organisations, and local populations have had significant ethical, health, social, political and economic implications for Africa during the twentieth century, with a spill over effect on research (Roets and Molapo, 2019). The continent faces a high burden of disease, socioeconomic and political instability, creating a need for a broad spectrum of research activities and foci. Furthermore, Africa is often used as a testing ground for biomedical research from developed countries (as in the current Covid-19 pandemic), with associated ethical issues to be considered. To this end, the guidelines address four vital, interrelated dimensions concerning responsible and ethical research governance (Figure 1). These dimensions - moral, professional, special considerations and statutory - apply to all types of research (Visagie, 2021).

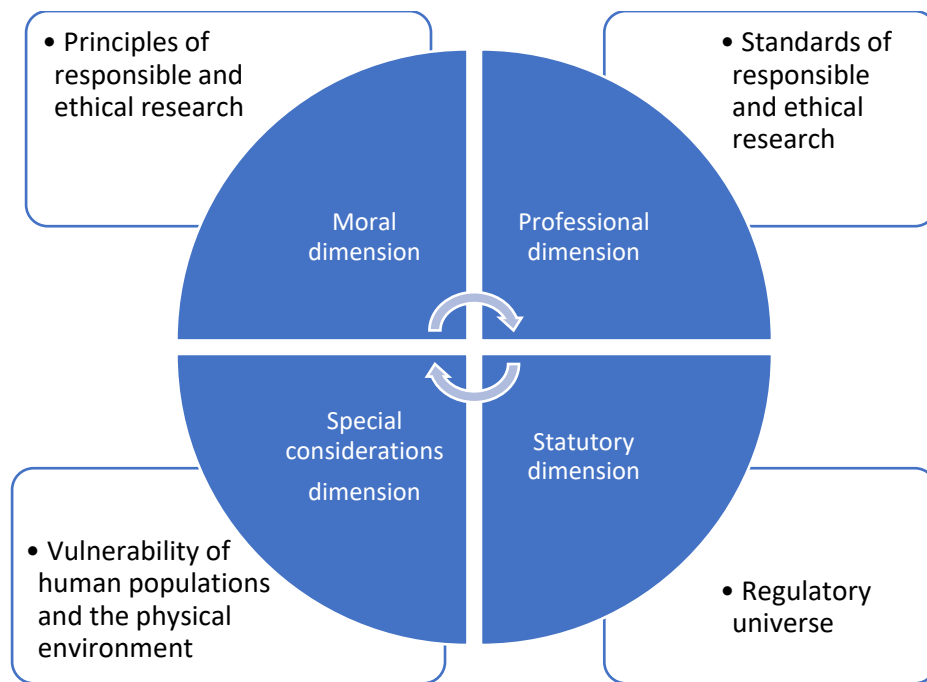


Figure 1: Framework to promote responsible and ethical research in the SADC region

The ‘moral dimension’ refers to internationally accepted principles to promote responsible and ethical research. With a renewed focus on Africa and the aim to affirm African cultures and their identity in the global context, this section integrates widely accepted international codes of conduct with a more localised focus, for example the San Code of research ethics (see section 2). The principles provide ethical convictions proposed as yardsticks to guide researchers’ decision-making and evaluate research protocols by research ethics committees (RECs). The ‘professional dimension’ provides the normative standards that follow these principles and guide researchers’ actions (see section 3). The ‘special considerations’ dimension highlights the importance of taking special care and precautions when vulnerable individuals, communities or environments are involved in research. The ‘statutory dimension’ provides an overview of relevant legislation, regulatory requirements and policy frameworks that researchers, RECs, research institutions and governments should consider concerning the governance of various types of research under their purview (see section 4). Section 5 provides an overview of the implementation of these interrelated aspects governing responsible and ethical research. Where possible, the Guideline and Toolkit aim to apply the framework to the following types of research:

- **Human research**

Human Research refers to any and all research involving human participants directly or indirectly to health, medical and non-medical research. This can vary from conducting surveys or questionnaires to such human participants providing personal information.

- **Health research**

According to the 2015 DoH Guidelines, “Health Research contributes to knowledge of biological, clinical, psychological, or social welfare matters including processes; causes and effects of and responses to diseases; effects of environment on humans; methods to improve health care delivery; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care.”⁸

- **Research involving traditional knowledge systems**

Indigenous Knowledge may have various definitions but the one that is mostly used in the SADC region is the one that states that it is “knowledge which has been developed within an indigenous community and has been assimilated into the cultural and social identity of that community, and includes (a) knowledge of a functional nature; (b) knowledge of natural resources; and (c) indigenous cultural expressions.”⁹

- **Animal research or animal studies**

Animal research or studies, according to the South African National Standard, include procedures performed on animals for the advancement of knowledge, to test a hypothesis, supply a product other than cosmetic products, produce a biological substance, provide tissues, organs, or serum, to act as a host, impact or demonstrate existing knowledge, teach or learn surgical techniques and to fulfil statutory requirements for the testing or collecting of data on a substance or product.¹⁰

- **Biodiversity and conservation research**

“Biological diversity (or biodiversity, as it has come to be called) refers to the variety and variability among living organisms and the ecological complexes in which they occur. Diversity can be defined as the number of different items and their relative frequency. For biological diversity, these items are organized at many levels, ranging from chemical structures that are

⁸ Department of Health, Republic of South Africa, 2015. “Ethics in Health Research: Principles, Processes and Structures”

⁹ Protection, Promotion, Development and Management of Indigenous Knowledge Act No. 1082 of 2019 s1

¹⁰ SANS 10386:2008

the molecular basis of heredity to complete ecosystems. Thus, the term encompasses different genes, species, ecosystems, and their relative abundance”.¹¹

- **Genetic and genomics research**

Genetic research¹² is the study of human gene (DNA), heredity and variation and how it affects inheritance of traits and conditions between generations of humans, especially regarding human health and disease. Genomic research¹³ is studying a person’s genome (i.e. genes) and how these communicate with each other and with one’s environment. This research allows for exploration into diseases at a population level to take into account genetic and environmental factors.

- **Community engaged research**

Community engaged research focuses on the generation of knowledge through community-based participatory research (CBPR) and participatory action research (PAR). It can involve quantitative, qualitative, or combined data gathering methods involving depending on the issues under investigation. Community engaged research implies an orientation to research. This orientation emphasises ownership, participation, access, control and possession by non-academic researchers/communities as values in the process of creating knowledge and change.¹⁴

Clinical research is not addressed in the Guideline and Toolkit considering the recently published CIOMS guidelines on ‘Clinical research in resource-limiting settings.’¹⁵

2. PRINCIPLES OF RESPONSIBLE AND ETHICAL RESEARCH

2.1 Research with human participants

Research integrity and ethics are the cornerstones of responsible and ethical research involving humans, communities, institutions and the environment. The principles below serve as a guide to promote responsible and ethical researcher behaviour and apply to health and non-health research

¹¹ OTA 1987, Available at <https://www.biodiversitylibrary.org/item/22847#page/3/mode/1up>

¹² Department of Health, Republic of South Africa, 2015. “Ethics in Health Research: Principles, Processes and Structures” p32

¹³ Department of Health, Republic of South Africa, 2015. “Ethics in Health Research: Principles, Processes and Structures” p32

¹⁴ UNISA 2016. “Policy on Research Ethics.”

¹⁵ Council for International Organizations of Medical Sciences (2021). Clinical Research in Resource-limiting settings. Available from: https://cioms.ch/wp-content/uploads/2021/06/CIOMS_ClinicalResearch_RLS.pdf

(science, social sciences, education and humanities). Furthermore, these principles are proposed as yardsticks to evaluate research protocols by Research Ethics Committees (RECs).

Table 2: Principles for responsible and ethical research

PRINCIPLE	DESCRIPTION
Duty to society	Researchers and research must contribute to the common good and well-being of society (Weinbaum et al., 2019).
Integrity	Researchers must be truthful in all aspects of research. They should avoid scientific fraud, misconduct, or questionable research practices.
Accountability	Researchers must fulfil their obligations to the various stakeholders in the research process and accept responsibility for their actions and the actions of members of the research team. Similarly, research institutions must create a nurturing research environment that cultivates responsible and ethical research.
Good stewardship and care	Researchers must honour commitments, engage in, and promote responsible and ethical research in their spheres of influence through practice, publishing, communicating, mentoring, and other activities. Care implies that research should be aligned with the local needs of communities and should, in certain situations, extend to the families of those involved, the social and physical environment. ¹⁶
Social awareness	Researchers and institutions must be sensitive to the potential influence of their research on society, marginal groups, and individuals. They must consider these when weighing the research benefits against any harmful effects to minimise or avoid the latter where possible. ¹⁷
Respect for persons and communities	Researchers are obliged to uphold individual human dignity without compromising collective and communal dignity. Human dignity incorporates the obligation to treat individuals with <i>reverential respect</i> (Tangwa, 2000) solely by being human. Researchers express dignity by treating individuals as autonomous agents, protecting the rights of persons with diminished autonomy, and creating a harmonious balance between individual and collective autonomy in research involving communities, thus acting as culturally sensitive moral agents (Visagie et al., 2019). Autonomy refers to the ability to deliberate and to act on a decision. Similarly, regulators and administrators should facilitate a regulatory culture that grants researchers the same level of respect that researchers should offer to

¹⁶ SAN Code of Research Ethics. 2017. TRUST. Available at https://www.globalcodeofconduct.org/wp-content/uploads/2018/04/San-Code-of-RESEARCH-Ethics-Booklet_English.pdf

¹⁷ ASSAf, CHE, DHET, NRF AND USAf. 2019. Statement on Ethical Research and Scholarly Publishing Practices. Available at https://www.nrf.ac.za/sites/default/files/documents/STATEMENT%20ON%20ETHICAL_0.pdf

PRINCIPLE	DESCRIPTION
	research participants. ¹⁸ The interest of researchers include their welfare and safety interests, authorship, intellectual property and collegial and professional interests.
Maximise research benefits	Researchers, Research Ethics Committees (RECs) and funders must protect the well-being of research participants, communities, animals, and the environment. The benefits of the research ought to outweigh the risks. To this end, research should be designed to maximise potential benefits, minimise potential risks, limit exploitation and stigmatisation of research participants or third parties, and promote social and scientific value of the research.
Equitable distribution of benefits and burdens (justice)	Researchers, RECs, funders and other stakeholders must ensure that the potential benefits and risks of research are equitably distributed amongst members of the society who are likely to benefit from it. Hence, individuals, groups, or communities invited to participate in research must be selected for scientific reasons and not because of their ease of availability ¹⁹ . There should be a reasonable chance that the population from which participants are drawn will benefit from the research finding, if not immediately, then in the future. ²⁰
Fairness	Researchers, RECs and institutions must strive to improve the fairness, efficiency and impact of research collaborations to promote global health, equity and sustainable development. In adherence to Sustainable Development Goal 17, ²¹ fairness includes considerations concerning fair opportunity, process, benefit-sharing, costs, and research outcomes. ²²
Protection of the environment, biosphere and biodiversity	The interconnection between humans and other forms of life must be considered, including appropriate access and use of biological and genetic resources, respect for traditional knowledge, and the role of human beings in protecting the environment, the biosphere, and biodiversity.

2.2 Research with animals

The principles below apply to research involving animals (Table 3).

¹⁸ The New Brunswick Declaration: A Declaration on Research Ethics, Integrity and Governance resulting from the 1st Ethics Rupture Summit, Fredericton, New Brunswick, Canada. 2013. Available at <http://www.sfu.ca/~palys/NewBrunswickDeclaration-Feb2013.pdf>

¹⁹ Council for International Organizations of Medical Sciences (CIOMS). 2016. International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Available at <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

²⁰ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

²¹ United Nations. Sustainable Development Goals. Available at <https://www.un.org/sustainabledevelopment/sustainable-development-goals/>

²² Council on Health Research for Development (nd). Research Fairness Initiative

Table 3: Principles for responsible and ethical research involving animals²³

PRINCIPLE	DESCRIPTION
Replacement	Methods that promote the replacement or partial replacement (for example, ex-vivo primary cell cultures) of the use of animals shall be investigated, considered and, where applicable, implemented. Before the use of animals are considered, all existing information relevant to the proposed aim(s), including existing databases, shall be examined. Replacement techniques to be considered include the use of epidemiological data; physical and chemical analysis; computer, mathematical and inanimate synthetic models; simulations; in vitro systems; non-sentient organisms; cadavers; and clinical cases.
Reduction	The number of animals used in a project shall be the minimum necessary to achieve the proposed aim(s) and satisfy a good statistical design. The use of too few animals may invalidate the experimental result and result in the wastage of animals. The appropriate reuse of individual animals may reduce the number of animals used. The benefits of reusing animals shall be balanced against any adverse effects on their well-being, taking into account the lifetime experience of the individual animal. Reuse of animals requires particular justification and specific REC approval. As a guiding principle, reducing the number of animals used should not result in greater harm, including pain, suffering, distress and lasting harm, to the individual animals used. The benefits of reducing the number of animals shall be balanced against any adverse effects on their well-being, taking into account the lifetime experience of the individual animal. This requires particular justification and specific REC approval.
Refinement	Steps shall be taken at all times to support and safeguard the animal well-being. The effectiveness of strategies for supporting and safeguarding animal well-being shall be kept under review during the lifetime of activities, including projects. Where relevant and applicable, the outcome of this review shall be implemented in current activities and taken into account in planning future activities, including projects. The duration of activities shall be no longer than required to meet the aim(s) of the project and shall be compatible with supporting and safeguarding animal well-being. Animals shall not be held for prolonged periods as part of an approved project before their use without the REC approval. Animals chosen for scientific purposes shall be suitable for the investigation, taking into account their biological characteristics, including behaviour, temperament, physiology, morphology, genetic constitution and nutritional, microbiological and general health status.

²³ South African National Standard for the care and use of animals for scientific purposes – SANS 10386:2008/2021

PRINCIPLE	DESCRIPTION
Responsibility	The institutions, the RECs, and the people involved in any aspect of the care and use of animals for scientific purposes shall be aware of and accept their responsibilities and act following local and international accepted standards.

2.3 Role of principles

The principles listed above provide a normative structure that guides the ethical analysis of research protocols by RECs during the review process. The ethics principles are drawn from international research ethics guidelines and inform the procedural rules in policies and procedures. Researchers ought to be knowledgeable about these principles and apply them during a research study's life cycle (Table 4). Furthermore, they are realised through specific standards or conditions set out in **section 3**.

Table 4: An overview of various categories of principles

CATEGORY	DESCRIPTION	PRINCIPLE(S)
Responsible and ethical research inquiry	The research must have social value and benefit society	Duty to society
Responsible conduct of research	Researchers should display professional competence and are responsible for acquiring knowledge and skills for conducting research ethically and by using appropriate research methods.	Integrity Accountability Good stewardship and care Social awareness Fairness
Ethical treatment of research participants	Research participants should be treated humanely according to accepted principles and standards. The secondary effects of the research should be considered.	Respect for persons and communities Maximise research benefits Equitable distribution of benefits and burdens (justice)
Ethical treatment of environments	Research must be conducted according to accepted principles and standards to protect the environment, biosphere and biodiversity. The secondary effects of the research should be considered.	Protection of the environment, biosphere & biodiversity

CATEGORY	DESCRIPTION	PRINCIPLE(S)
Ethical treatment of animals involved in research	Animals should be treated humanely according to accepted principles and standards. The secondary effects of the research should be considered.	Replacement Reduction Refinement Responsibility (Table 2)

Table adapted from Weinbaum et al. (2019)

3. STANDARDS OF RESPONSIBLE AND ETHICAL RESEARCH

The following section describes the normative standards that researchers can apply to promote responsible and ethical research. The inclusion of these standards in research protocols provides RECs with vital information to guide their decision-making.

3.1 Decision-making and addressing responsible and ethical research

Independent RECs need to be established to review the various types of research (human and health research, research involving traditional knowledge systems, animal research, biodiversity and conservation, genetic and genomics research and community-engaged research). Professionalism, integrity, and transparency in decision-making should be promoted, particularly the declaration of conflicts of interest.²⁴ In the spirit of collegiality and care, research ethics committees and researchers should work together to promote research ethics and ensure a frank and comprehensive ethical assessment of the research to ensure the protection of participants and researchers.²⁵ Standards for ethics review for human and animal research include:

- a critical review of the research protocol that stands up to scientific and ethical scrutiny applicable to the disciplines concerned,
- due consideration of relevant ethical, legal, scientific, health and social issues relating to the proposed research using this Guide (or similar guidelines) as a minimum benchmark,
- approval and monitoring by the REC,
- commencement of a study only after approval has been granted by the REC,
- the execution of research procedures and activities in accordance with the REC approval, and

²⁴ United Nations Educational, Scientific and Cultural Organization. 2005. Universal Declaration on Bioethics and Human Rights. Available at <http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/>

²⁵ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

- termination or halting of a study if approval from the REC is suspended or withdrawn.

3.2 Relevance and social value

Research needs to show relevance and respond to the needs of SADC countries, thus aiming to improve the wellbeing of the population or specific group taking part in the study. Emmanuel et al. (2004) identify four standards in clinical studies that can be adopted for various research studies:

- The anticipated contribution of the study must be explained, including the immediate and future hypothetical beneficiaries. Will the research only benefit the host country or people outside the host country, or will the local community benefit from the study?
- The potential value of the research for each of the prospective beneficiaries needs to be described and outlined. What are the mutual terms of the agreement between all the parties involved?
- The social value of the research needs to be enhanced through collaborative partnerships and strategies. Responsible publishing of results in open access repositories could improve the relevance and societal value of research results.
- The study needs to improve the existing settings and not undermine the community or group's current system. Will the research supplement the existing system through additional resources, equipment, medication, or training? How might the findings be translated into products, services, or interventions to improve people's lives in a specific setting/country?

3.3 Researcher competence and expertise

Researchers need to take reasonable steps to ensure their work's competence and protect research participants, animals, society, and the environment from any harm. Researchers need to accept professional responsibility for their work and the work of their colleagues that fall under their supervision (Weinbaum et al., 2019):

- Only do work that is falling under your competence level,
- Do not claim any competence or expertise that you do not possess,
- Develop professional skills and competence in technicalities and standards applicable in your field of expertise,
- Know all legislation and comply with legislation in your field of work,
- Respect alternative viewpoints of peers and seek, accept and offer honest criticism of work,

- Avoid harming others, their reputation, property, or employment by the false or malicious, or negligent action or inaction, and
- Reject and do not make unethical undue inducement or bribery offers.

3.4 Scientific validity

For research to be ethical, it must be scientifically valid, irrespective of the discipline. A sound design and methodology will likely result in reliable and valid data, which should yield fruitful results for the good of society. Poor design and unsuitable methods may create an unnecessary risk of harm to participants and waste resources with little or no benefit concerning knowledge generation.²⁶ The researcher and REC must consider the ethical implications of the research design and methods of a research protocol. Even if a scientific review has occurred, the REC must assess how the research will be conducted, whether the researchers are suitably qualified, if adequate monitoring and safety measures are in place and achievable, if the site is adequately resourced, and if the research procedures will not result in undue harm.²⁷ In a setting where a prior scientific review cannot be done, the REC is responsible for conducting a dual review, including a review of the ethical implications and the scientific validity of the research.

3.5 Scientific integrity

Researchers must display the quality of being honest (integrity) throughout the lifecycle of their research, including reporting on their work. The Hong Kong principles (Moher et al., 2020) aim to foster scientific integrity by recognizing researchers who commit to robust, rigorous and transparent practices. The following indicators of the research process are highlighted:

- Study Formulation: Exploratory or confirmatory, valuable and relevant research that builds on previous findings,
- Study Design: Reduces publication and other reporting bias; Enhances reproducibility; Specifies exploratory and confirmatory parts,
- Study Conduct: Allows data aggregation, re-use and transparency,
- Analysis: Enhances reproducibility; Separates data-driven analysis and hypothesis testing,
- Reporting and Publication: Enhances openness and accessibility; Specifies exploratory and confirmatory findings with social sensitivity and aligned to study objectives, and

²⁶ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

²⁷ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

- Dissemination: Focuses on outcomes, subsequent studies, knowledge transfer and impact of research.

3.6 Role-player engagement, collaborative research and mutually agreed terms (MATs)

Researchers should engage important role players at various stages of planning and conducting research to improve the research's quality and rigor, increase its acceptability to the key role players, harness role player expertise where possible, and offset power differentials where these exist. Various activities, such as awareness-raising initiatives for role players, including but not limited to participating communities, may be included in engagement efforts.²⁸ Research collaboration is often misunderstood to be limited between researchers and institutions. Yet, collaborative research must be understood within the broader context and researchers must be mindful of why it is necessary and intended. Within the Nagoya Protocol context, collaborative research is inherently a partnership that recognizes that the communities where the research takes place must be engaged in the research enterprise and ensure that these communities are not exploited. Instead, communities determine if the research is acceptable relevant to their communal needs. Therefore, community advisory boards (CABs) are crucial if the research collaboration is to have a lasting effect. In collaborative research, where boundaries of disciplines, institutions or nations are crossed, it is important to identify and declare conflicts of interest and to manage mutually agreed terms and role player engagement.

The following responsibilities apply in cross-boundary²⁹ and other research collaborations:

- Mutual trust and goals: Collaborating partners should take collective responsibility for the trustworthiness of the overall collaborative research with mutually agreed terms and goals. Thus, how will the collaborating partners share responsibilities for planning, conducting the study, disseminating the results and using the results to improve livelihoods?
- Communication and compliance: Collaborating partners should communicate openly and foster mutual understanding of the goals and all necessary legislation compliance,
- Roles and responsibilities: Collaborating partners should understand their roles and responsibilities in the planning, conduct, and dissemination of research. Which community representatives/partners will be involved in the planning, conducting, results dissemination, and usage of the information?

²⁸ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

²⁹ Montreal Statement. 2013.

- Legal implications: Institutions and researchers must have a clear understanding of binding legal implications of Mutually Agreed Terms and/or Memorandums of Agreements. Researchers should not be signing any documents on behalf of Ministries or Research Institutions - this should be the responsibility of designation authorised signatories.
- Conflict: Collaborating partners should seek prompt resolution of conflicts, disagreements and misunderstandings at the individual or institutional level,
- Outcomes of research: Collaborating partners should agree on the fair use, management and sharing and ownership of the data, intellectual property and research records. This includes how the tangible benefits (i.e., authorship credit, intellectual property rights) and intangible benefits (training, employment, health facilities) will be fairly distributed,
- Accountability and authorship: Collaborating partners should come to the agreement of standards for authorship and should be accountable to each other, to funders and to stakeholders in the accomplishment of the research, and
- How will respect for the communities' values, circumstances, culture and social practices be considered?

3.7 Fair selection of participants

The participant selection process is a concrete way of applying the ethics principle of justice in research. This is also called the fair distribution of anticipated risks and potential benefits of participating in research.³⁰ The selection of research participants must be fair. The inclusion of a study population needs to carefully align with the study objectives and the specific inclusion and exclusion criteria as set out in the research design. The choice of the study population needs to be based on scientific considerations, it needs to minimize risk and the targeted population also need to share in the benefits. In using populations with special needs or in a situation of vulnerability, scientific justification is required. The sample size is a crucial part of the study design to ensure that study findings are sufficient without overburdening an excessive number of participants. New technologies make it possible to work smarter and findings could be enhanced and simulated. A strategy of less is more needs to be adopted.³¹

³⁰ World Medical Association (WMA). 2013. Declaration of Helsinki. Ethical principles for medical research involving human subjects.

³¹ Council for International Organizations of Medical Sciences (CIOMS). 2021. A consensus by a CIOMS Working Group. Geneva 2021.

3.8 Informed consent

In allowing research participants to exercise their free and informed choice to participate in a research study, researchers uphold the principle of autonomy in research ethics. Informed consent should be understood as a process and not a single event.³² Information can be shared and discussed in various ways before a prospective participant decides to participate in a study. Valid informed consent lies on four key elements:

- **Capability:** Research participants need to be mentally capable to consider participation considering personal goals, values and preferences,
- **Competency:** Competence refers to legal capacity to allow or refuse participation. When prospective participants lack capacity and/or competency to decide, additional safeguards are required,
- **Informed:** Various information needs to be provided to prospective participants to make an informed decision (see Toolkit document), and
- **Voluntary:** Prospective participants must be free to choose whether to participate in a research study and need to know that they are free to withdraw from the project at any time without the fear of any reprisal.

There are exceptions and exceptional cases where the normal valid informed consent process cannot be followed. In these cases, special consent is needed from gatekeepers or substitute decision-makers who may grant proxy consent:

- **Infants and very young children and orphans:** Such individuals are incompetent to make fully informed decisions. In such cases, the researcher should seek assent from the parents or guardian of the child. The legal age of children to grant consent to partake in research differs from one country to the other,
- **Individuals with severe developmental, mental or dementia or other health conditions:** Cases differ, and the researcher should seek guidance from the institution or legal guardian. Special justification for the inclusion of these individuals will be needed by RECs and proxy consent made by the substitute decision-maker, and
- **Captive populations:** Here, individuals may be fully competent to decide about participation in research, but their voluntary participation could be questioned. These could include prisoners,

³² Council for International Organizations of Medical Sciences (CIOMS). 2016. International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva.

military personnel, institutionalized senior citizens and refugees in camps. This is also referred to as dependent relationships and individuals are not free to participate as refusal could lead to punishment or withholding care and basic needs. In these cases, researchers will need to take special care to ensure that participation in the research is voluntary.

In special cases, it is also possible to request a waiver of consent. Only RECs may approve a waiver of consent with suitable justification from the researcher. Emergency research on patients where new treatment could be more promising than existing standard treatment may justify a request for delayed (rather than waived) consent. Permission needs to be obtained as soon as possible from the patient or legal substitute decision-maker. A waiver of consent may be requested in cases where data or biological specimens are not personally identifiable and the research have social value.

Studies that use any form of deception of participants, concealment or covert observation, needs justification and will have to receive the consent of the participants retrospectively and needs to have a referral system for participants, where applicable.

Potential participants should be given written information on an information sheet, detailing specific information about the nature of the research study, including any risks or benefits associated. If a decision is reached to participate in the study, participants should give their consent in writing and preferably accompanied by their signature or a thumb print. If participants do not want to provide their consent in writing, consent may be recorded verbally, provided that verbal consent can be linked to the individual providing such verbal consent, which should be ideally captured digitally through audio recording. For example, where a participant is illiterate, consent may be obtained in the presence of a literate witness who should verify and sign a document stating that informed consent had been given. Under certain circumstances, for instance, in the context of health-threatening situations, obtaining informed consent might not be possible or safe (for the participant and/or researcher). Irrespective of the method used, the consent process needs to be well-documented and evidence of the verbal or audio signing needs to be stored in a safe place.

3.9 Privacy and confidentiality

Privacy and confidentiality of personal information that is not for public viewing is part of the promotion of the human dignity of research participants and is an internationally recognized norm and ethical standard. Researchers need to ensure that the research participants' confidentiality will be maintained throughout the research process. A researcher must ensure that personal information

of research participants are protected during the data collection, data sharing and data storage phases of the project. Researchers need to consider the following when they collect personal data from research participants:

- The type and purpose of the data that will be collected,
- The limits of the use, disclosure and storage of the data,
- Appropriate safeguards for security and confidentiality,
- The use and storage of visual or sound recordings that could identify research participants,
- Who will have access to the data and did they sign confidentiality agreements?
- Will there be any secondary use of identifiable information? and
- Provisions made for the confidentiality of data in research reports.

3.10 Risk-benefit assessment and management

The ethics principles of beneficence (do good) and non-maleficence (do no harm) are actualized through standards that would bring about more good than harm in the research process. Any research project has potential benefits and risks of harm associated with the process. The accompanying Toolkit document discusses risk-benefit analysis.

Potential benefits in a project may be directly, indirectly or relating to benefits to society:

- Direct benefits: Participation in the project have the potential to directly benefit the research participant, e.g., a new treatment for a disease,
- Indirect benefits: Participation in the project may deliver indirect benefits, e.g., medical examination as part of being on the study; or participating in a peer group may assist in experiences of social value, and
- Other benefits: To partake in the project could assist the environment, or health sector or work environment of an individual. Research participation is purely altruistic to serve a more profound concern for the well-being and happiness of other people.

Risk of harm is the potential for an adverse or adverse severe outcome when taking part in research. There are several potential risk categories relating to research participation:

- Physical harm: Participation in a research study or clinical trial may harm the person. It can cause injury, pain, disability or have serious side effects,

- Psychological harm: Participation in a research study may cause anxiety, emotional distress, reactivation of trauma or embarrassment,
- Social harm: Participation in a research study may cause stigmatisation or a breach of confidentiality of a peer group or a relationship,
- Economic harm: Participation in a research study may cause a loss in wages or income when the participant is away from work,
- Indirect harm: Participation in a research study may cause harm to “third parties” such as an unborn foetus or a community (harm by association), and
- Reputational harm: The research may harm the integrity and reputation of an institution relating to the findings of a study or the use of research procedures that caused direct or indirect harm to the participants or the population to which the participants belong. Therefore, the risk of harm should also include the interests of institutions, communities and society as a whole.

The management of the risk of harm is a critical element of the research ethics review process done by RECs through a risk-benefit analysis. The ratio of the risk of harm to the likelihood of benefit should be acceptable. A good risk-benefit analysis depends on a protocol meeting the following standards:

- the harms and benefits are adequately identified, evaluated and described,
- the harms stated in the proposal match those stated in the informed consent documentation;
- the risk of harm is reasonable in relation to anticipated benefit,
- the risk of harm is reasonable in relation to the importance of the expected knowledge to be gained, and
- counselling and support services will be made available if appropriate.³³

RECs also need to consider the potential risks of harm for the researcher and research team. The following information is required to assess the risk for the researcher(s) and field workers:³⁴

- Is there a possible risk of physical threat, abuse, or psychological trauma resulting from actual or threatened violence or the nature of what is disclosed during the interaction?
- Is there a possible risk of being in a compromising situation in which there might be accusations of improper behaviour?

³³ Department of Health, Republic of South Africa, 2015. “Ethics in Health Research: Principles, Processes and Structures”

³⁴ UNISA 2016. “Policy on Research Ethics.”

- Is there an increased exposure to risks in everyday life and social interactions, such as working with hazardous materials, sensitive information, or in an environment where personal safety may not be guaranteed?

3.11 Reimbursement and inducements

Participants should not have to incur expenses to take part in a research study. Consequently, researchers should ensure that a budget is available to reimburse any costs incurred by participants for travel, refreshments, and inconvenience, depending on the circumstance and on the nature of the investigation. A fair reimbursement rate should be calculated using the Time, Inconvenience and Expenses (TIE) method. Financial inducements are used in some instances to encourage participation, and may be relevant for some types of studies, such as those where recruitment of participants is anticipated to be complicated. However, financial inducements are not encouraged: a justification for this approach should be provided by all applicants and any financial inducement should not unduly influence participation or increase the potential risk of harm to the participants.³⁵ In some instances, gatekeepers have a role in gaining access to a participant community. In some instances gatekeepers might expect an inducement or contribution

3.12 Traditional Knowledge, Conservation and Biodiversity

The United Nations Permanent Forum on Indigenous Issues (2019) describes traditional knowledge as knowledge, innovations and practices of indigenous and local communities around the world. This knowledge developed from experience gained over the centuries and adapted to the local culture and environment. Article 3 of the Nagoya Protocol is clear that traditional knowledge will not always be accessed in combination with a genetic resource. Instead, a potential user can in certain instances only access the traditional knowledge and not the genetic material associated with it. Governments and regulators must ensure the generation, transmission, protection, maintenance and strengthening of traditional knowledge through legislative, administrative or policy measures (IUCN Environmental Policy and Law Paper No. 83).

The Bonn ABS MT (2005) refers to three aspects that should be considered when traditional knowledge is accessed:³⁶

³⁵ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

³⁶ Available at https://www.iisd.org/system/files/publications/abs_mt.pdf

- i) The integrity of traditional knowledge associated with genetic resources that are accessed is respected by the user,
- ii) Fair and reasonable effort is made to preserve, respect and maintain traditional knowledge associated with genetic resources when that traditional knowledge is accessed and used, and
- iii) Adequate compensation and sharing of benefits are provided, including a recognition of the community that holds the specific traditional knowledge associated with the genetic resource being accessed and used.

As the protection of traditional knowledge varies between countries, in accordance with national legislation, policy and practices, it is important to consult with the competent national authorities. Researchers (whoever/wherever they come from) should work collaboratively with local partners and stakeholders, including local communities and/or local leaders.

The Nagoya Protocol³⁷ indicates that researchers and institutions that approve research studies should adhere to the following guidelines:

- To create conditions or promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries,
- To pay attention to cases that present or could threaten or damage human, animal or plant health, as determined nationally or internationally,
- To take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries, and
- Consider the importance of genetic resources for food and agriculture and their special role for food security.

Researchers should include the benefit-sharing arrangements in research protocols and Informed Consent documentation submitted for review by RECs. Any legal agreements lie outside the remit of RECs and must be negotiated with relevant stakeholders prior to applying for research ethics approval.

³⁷ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits. 2011. Published by the Secretariat of the Convention on Biological Diversity, Canada.

4. SPECIAL CONSIDERATIONS: VULNERABILITY

Some countries in the SADC region acknowledge the vulnerability of research participants or subjects. In this regard, research participants are human or animal, or plant subjects. For example, the South African National Department of Health (DoH) Ethics Principles in Health Research Guidelines (2015)³⁸ clearly states that certain groups or special classes of participants require careful consideration to ensure that, where appropriate, additional precautions are put into place. For example, advanced age, very young age, personal or environmental factors like extreme poverty and poor access to health care may increase vulnerability.

While Nortje et al. (2019) rightfully argue that there is scholarly disagreement over the appropriate meaning and application of the concept of vulnerability in research ethics, here are some acceptable definitions of vulnerability:

The South African DoH (2015) guidelines define vulnerability as: “diminished ability to fully safeguard one’s own interests in the context of a specific research project; may be caused by limited capacity or limited access to social goods like rights, opportunities and power.” The CIOMS guidelines³⁹ provide a broader description of vulnerability as “characteristics and circumstances that may render individuals vulnerable such as the limited capacity to consent, subordinate position in a relationship, institutionalisation, or being a refugee and additional measures that can be taken to protect vulnerable persons individually or collectively in research. This involves judgments about both the probability and degree of physical, psychological, or social harm, as well as a greater susceptibility to deception or having confidentiality breached.”

Furthermore, Kruger et al. (2014) state that “a vulnerable research participant is someone who, because of some characteristic or prevailing set of circumstances, is at risk of being exploited or harmed in the course of biomedical research. Research ethics committees (RECs) must take special care when approving research involving vulnerable research participants or communities.”

The DoH guidelines (2015) recommend that the highest priority is refinement of ethics guidelines, establishment of research ethics and animal research ethics committees, and strengthening of review processes to protect the rights, safety and welfare interests of individuals involved in research,

³⁸ Department of Health, Republic of South Africa, 2015. “Ethics in Health Research: Principles, Processes and Structures”

³⁹ Council for International Organizations of Medical Sciences (CIOMS). 2016. Ethical Guidelines: Clinical research in resource-limited settings. A consensus by a CIOMS Working Group.

particularly vulnerable participants; to protect the welfare and safety interests of animals used in research; and to protect safety and other interests of researchers.

These guidelines provide guidance about the different types of research or specific research participants that require thorough treatment in light of particular sensitivities or vulnerabilities. In terms of inclusion and exclusion criteria, researchers are required to provide an adequate justification for the inclusion of vulnerable participants. The CIOMS guidelines (2016) make provision for special groups of research participants that are vulnerable mainly include women and children, especially in low resourced environments. In addition, these guidelines recommend that governments and regulatory authorities establish and then also enforce effective regulations for ethical review; ensure appropriate protection, which does not mean exclusion, of vulnerable persons and groups in research.

4.1 Contextual circumstances

In this regard, personal and environmental circumstances should be considered. Personal circumstance relates to, for example, a person ability or inability to understand the research and to provide informed consent. For example, mental or intellectual impairment may prevent a prospective research participant from fully comprehending the proposed research information and truly giving informed consent. In addition, environmental circumstances such as poor economic conditions, low levels of formal education and literacy, or restricted access increase vulnerability. It is generally accepted that such persons may more easily be coerced to participate in the proposed research. For that reason, special attention is required to ensure that the rights of the research participants are protected. The safeguard or gatekeeper role of research ethics committees is paramount to ensure that prospective research participants will not be exploited or coerced.

4.2 Traditional medicine research

Traditional medicine research requires careful consideration for cultural and language rights, and that indigenous cultures and traditional values of all communities must be respected. Therefore, prospective research participants involving traditional medical systems and beliefs must be given the same respect and protection as any other human research participant. The context of the research activity, interaction or intervention is important for determining whether, how and when traditional values and their cultural expression should be considered in the research, and how. Individuals or member of a community holding knowledge or traditional medicine should be protected and safeguard measures are therefore required.

Traditional medicine refers to the knowledge, skills and practices based on the theories, beliefs and experiences that are indigenous to many cultures and may be used in primary health care practice if traditional medicinal products are standardised and evidence-based. Ethical issues regarding traditional medicine research involve social value, scientific validity, and risk-benefit assessment (Kruger et al., 2014).

4.3 Research with minors

In many SADC jurisdictions, most countries define a child to be a person under the age of 18 years of age. In SADC, children and youth constitute the majority of the population.⁴⁰

Given the legal definition of a child, children may not be able to legally consent on their own. In addition to obtaining consent from the child's parent, legal guardian, or caretaker, the child's willingness to participate or cooperate must always be obtained. This willingness to participate in a research study by a minor is called *assent*. In the context of research, a vulnerable research participant is an individual, or a group of individuals (such as minors) that are at potential risk of being exploited or harmed during the research project. This places an extra obligation on the REC to ensure that risk of harm is minimised and, in particular, that the validity of the consent process is maximised (Kruger et al., 2014).

The CIOMS guidelines⁴¹ make provision for assent whereby children and adolescents who are legally minors cannot give legally valid informed consent, but they may be able to give assent to participate. To give assent means that the child or adolescent is meaningfully engaged in the research discussion in accordance with his or her capacities. Assent must be considered as a process (see Guideline 9 – Individuals capable of giving informed consent) and is not merely the absence of dissent. Furthermore, the researcher must involve the child in the actual decision-making process and use age-appropriate information and language. It is important to inform the child and to obtain assent as described above, preferably in writing for children who are literate. The process of obtaining assent must consider not only the age of children, but also their individual circumstances, life experiences, emotional and psychological maturity, intellectual capabilities and the child's family situation.

⁴⁰ SADC Regional Assessment Report of Policies and Programmes for Child and Adolescent HIV, TB and Malaria. 2013. Available at https://www.sadc.int/files/1114/1898/8392/SADC_PD_S9_Children_Assessment_Report.pdf.

⁴¹ Council for International Organizations of Medical Sciences (CIOMS) 2016. Available at https://cioms.ch/wp-content/uploads/2021/06/CIOMS_ClinicalResearch_RLS.pdf

Vulnerability exhibited by participants in the informed consent process is a reality, especially in the African context where socioeconomic, ethic, cultural and political power, coercion and literacy/language issues may be present. Voluntary informed consent by participants should be an ongoing activity during every stage of the research process, and this can ensure that voluntary participation is present during all stages of the research. (This also includes minors as research participants). Thus, it is important that ethical principles are observed when collecting data from human participants, including ensuring that consent is voluntary and informed (Nortje et al., 2019).

International and regional guidelines make provision for various groups of participants as being potentially vulnerable under some circumstances and with respect to some types of research investigations. Commonly, the demographic groups identified are children, pregnant women and foetuses, persons with mental disabilities, and prisoners, amongst others, although this list varies by different sources. The general consensus is that children are always considered as a vulnerable research group owing to their evolving decision-making capacity, which is usually embedded in a legal framework with the age of majority being 18 years of age in most cases. This means that many countries have specific laws that regulate the involvement of minors as research participants. RECs must therefore be familiar with relevant national and international regulatory frameworks for the involvement of such participant groups, particularly where the research is funded by an external funder or where participants are being recruited in several countries/jurisdictions (Kruger et al., 2014).

While the definition of a child refers to children under the age of 18 years of age, adolescence require special attention, too. There is no formal definition of adolescents (usually defined according to some age category), but they are a particular group of minors that may pose challenges regarding consent. RECs may consider a waiver of consent if the age of majority is recognised as being reached at a younger age in a particular country or in the context of child-minded families, where the child, who heads the family, is deemed competent, and where the child can consent to receiving medical treatment, similar to the research, without parental consent. Many countries also specify the age at which a child can marry, which may also be a useful guide here. In such cases, the REC should have to determine whether the child has the capacity to provide informed consent, especially in the context of certain types of research (Kruger et al., 2014). In certain circumstances, RECs may waive parental permission, depending on the nature of the study. Examples include studies investigating sexual activity, drugs etc. In such cases, special protections and support services must be put in place to ensure that the best interests of these children or adolescents are being served, and that ethics applications justify why certain things are being done or not done in that particular study. These

circumstances might include cases in which permission of a parent is not feasible or is undesirable, depending on the nature and aims of the research study. This can be evaluated using a risk benefits analysis. In some jurisdictions, certain individuals who are below the general age of consent are regarded as “emancipated” or “mature” minors and are authorised to consent without the agreement or even the awareness of their parents or guardians. They may be married, pregnant or be parents themselves, or they may live independently.⁴²

The notion of the best interest of the child is important and should be foremost when ethics applications dealing with such studies are considered. In some SADC countries such as South Africa, the Constitution of the Republic of South Africa⁴³ and the Children’s Act⁴⁴ protects children’s rights and that their best interest is paramount. In fact, some SADC countries, including South Africa, are signatories to the United Nations Convention on the Rights of the Child.⁴⁵ This Convention, too, protects the rights of children and promotes the best interest of the child. For SADC nations who do not have similar national legislation in place, this Convention may be useful.

There are also children who are more vulnerable than other for example, dying children, orphans, or children from severely poverty-stricken communities. These children require additional protection, including that of paediatric expertise on the ethics review committee. This class of vulnerable groups may also require additional protection in the form of an ombudsman or physician who is not part of the research team to monitor the research process in the best interest of the individual child (Kruger et al., 2014).

4.4 Safeguard research participants: the role of researchers and RECs

The SADC region is home to a number of vulnerable communities. Where factors usually associated with vulnerability are integral to the research, the research proposal should demonstrate how vulnerability would be managed. Therefore, it is paramount that researchers should include safeguard measures in the research proposal to acknowledge and protect the rights of prospective research participants. In this regard, the role of research ethics committees is to consider these measures to ensure that the rights of prospective research participants (individually or collective as a community) are protected.⁴⁶

⁴² Council for International Organizations of Medical Sciences (CIOMS). 2016. Ethical Guidelines: Clinical research in resource-limited settings. A consensus by a CIOMS Working Group.

⁴³ Act 108 of 1996 – Chapter 2: Bill of Rights

⁴⁴ Act 38 of 2005

⁴⁵ Available at <https://www.unicef.org/child-rights-convention>

⁴⁶ Department of Health, Republic of South Africa, 2015. “Ethics in Health Research: Principles, Processes and Structures”

4.4.1 The role of researchers

Researchers must provide protective safeguards for consideration by research ethics committees and these must be submitted and presented in full in any research ethics application. Inclusion and exclusion criteria of participants have ethical implications (e.g. fairness of selection) and are not just of scientific relevance. As a potential safeguard measure, researchers should treat information of research participants and research data with the highest confidentiality to prevent a situation where research participants may become vulnerable to potential or actual harm. Researchers are encouraged to probe prospective research participants' understanding and comprehension of information of the proposed research, especially of vulnerable research participants.

4.4.2 The role of RECs

Particular caution should be exercised before undertaking research involving participants from vulnerable communities. Based on the South African Department of Health guidelines,⁴⁷ RECs should ensure that:

- Persons in these communities are not being involved in research merely because they are expediently accessible, while the research could be carried out in a less vulnerable community,
- The research is relevant to the health needs and priorities of the community in which it is to be carried out, and
- Research participants know they will take part in research; and that the research will be carried out only with their consent. Particular attention should be given to the content, language(s) and procedures used to obtain informed consent.

RECs should avoid patronising assumptions about a community's ability to make responsible decisions. Factual information is required before deciding that a community is too vulnerable to be invited to choose whether to participate in research. In order to ensure optimal protection of vulnerable participants, the REC may impose additional protective measures for the informed consent process; or require increased monitoring and interim reporting on participants' welfare; or require post-recruitment reviews of the effectiveness of the protective measures imposed. Other measures may also be appropriate. Note that the decision to impose additional measures should flow from an assessment of the nature of the research and the circumstances of the potential participants. In other

⁴⁷ Available at <https://www.sun.ac.za/english/research-innovation/Research-Development/Documents/Integrity%20and%20Ethics/DoH%202015%20Ethics%20in%20Health%20Research%20-%20Principles,%20Processes%20and%20Structures%202nd%20Ed.pdf>

words, additional protective measures should not be automatic just because a vulnerable group will be recruited; rather, the decision should be based on the particular circumstances of the proposal before the REC. For example, an automatic assumption that impoverished people cannot choose responsibly whether to participate in research is disrespectful because it denies their autonomy.

RECs should ensure that researchers provide a clear justification for involving vulnerable persons or groups in their research. In particular, the rationale is not motivated by such factors as expedience, convenience, or lower cost. The CIOMS guidelines require that the following criteria be satisfied before ethics approval for the proposed research can be given:

- The research cannot be done involving a less vulnerable group,
- The research is directly relevant to the needs and the health concerns of this particular group,
- The research participants will have reasonable access to the benefits of the research, such as to new diagnostic or therapeutic modalities (Kruger et al., 2014).

Nortje et al. (2019) describe the role of RECs in detail, which is reproduced here. RECs play a pivotal role in ensuring that the principles of protecting vulnerable participants and preventing harm are always at the centre of the ethical review process. They guard against exploitation by ensuring that the research cannot be conducted with non-vulnerable groups, and that children and prisoners' participation is crucial to the research. The participants' benefits should be at the centre of the decisions on whether or not the study should be sanctioned. The role of RECs goes further to ensure that the quality of research activities do justice to the participants. Therefore, RECs should provide guidance on the protection of the vulnerable groups and at the same time provide guidance and mentorship of researchers on how best the studies could be improved to make the lives of participants better. They can thus play a special role in empowering researchers to be sensitive in communicating their awareness of the multiple vulnerabilities involved and explicating the strategies to address these. Given the unbalanced power relationships involved within these groups, RECs must assure that they protect participants and not the organisations in which they function. In some instances, the REC may choose to waive the strict adherence to consent in situations where some of the players in the lives of the vulnerable groups may be themselves perpetrators of the topic under investigation (e.g. abuse by a family member, teachers, or prison officials). Therefore, it is of the utmost importance that representatives from vulnerable groups be included in the REC decision-making process (Nortje et al., 2019).

5. SADC RESEARCH REGULATORY UNIVERSE

5.1 General overview – International perspective

A researcher, research institution and/or government wanting to conduct research in the SADC region in terms of the Nagoya Protocol and according to ethics guidelines, should first consider their institution's policies and procedures, then proceed to explore the following broader pieces of legislation, regulations, strategies and/or guidelines on an international level. Please note that the utilisation of biological and genetic resources is multifaceted as there are various ways in which these resources may be utilised and by different user communities.

5.1.1 The United Nations Convention on Biological Diversity 1993 (CBD) (as updated)⁴⁸

The starting point for any research to understand the international framework for access and benefit sharing is the CBD (2011). The CBD was established with three objectives: the conservation of biological diversity, the sustainable use of the components of biological diversity, and the fair and equitable sharing of the benefits arising from utilising genetic resources. Provisions were specifically included to meet the needs of developing countries. Two protocols are linked to the CBD that account for the needs of the developing countries and account for such needs by other countries. The two protocols are the Nagoya Protocol (as further explored herein) and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity 2000 (which governs the activities of living modified organisms resulting from modern biotechnology from one country to another country).

The NP is an international framework for the fair and equitable access and benefits sharing of genetic and biological resources and the transfer of particular technologies, including the rights and obligations over such resources, which results in the conservation of biological diversity and sustainable utilisation by indigenous communities and their traditional knowledges.⁴⁹ In the SADC context, this is the means to deliver compliance with principles of the NP through national-scale legislative and management frameworks. The NP covers indigenous knowledge linked to genetic resources that are covered by the CBD and any benefits arising from such utilization.

⁴⁸ United Nations LDC Portal International Support Measures for Least Developed Countries, Convention on Biological Diversity (CBD) and Protocols. <https://www.un.org/ldcportal/convention-on-biological-diversity-cbd/>

⁴⁹ United Nations, "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity" <https://www.cbd.int/abs/about/#importance>

5.1.2 UN Global Declaration on Human Rights of Indigenous People 2007⁵⁰

Indigenous peoples have been seen to be amongst some of the most vulnerable in the world. This Declaration addresses the rights of the indigenous people to maintain and strengthen their own institutions, cultures and traditions. The Declaration is to pursue the development of indigenous peoples in keeping with their own needs and aspirations. These rights include but are not limited to individual and collective rights regarding cultural, educational, health, and language and identity rights. The Declaration is to reinforce human rights and fundamental freedoms in the context of their indigenous environment and not be exploited through their lands, territories and resources.⁵¹ This Declaration prescribes minimum standards for the survival and dignity of such indigenous peoples.

5.1.3 2002 Bonn Guidelines⁵²

The 2002 Bonn Guidelines were drafted with the intention to assist Governments with the adoption of measures to govern the access and benefit sharing in their respective countries. As the name states, these are to guide countries, as both providers and users of genetic resources, to implement procedures for access and benefit sharing efficiently. These are voluntary guidelines but are vital in the implementation of the CBD in terms of the access and benefit sharing to genetic resources as they ensure the transparent framework of fair and equitable terms.⁵³

5.1.4 Belmont Report 1979⁵⁴

The Belmont Report outlines ethical principles and guidelines for the protection of human subjects of research. This Report was created and drafted by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the USA. It resulted from the USA's National Research Act of 1974. It is to regulate the utilization of experimentation in medicine on human subjects which is based on the basic ethical principles that should underpin the conduct of research in biomedical and behavioural research conducted with human subjects. The Belmont Report is often used as the basis for equivalent actions by other countries subsequent to 1979.

⁵⁰ United Nations Human Rights and Asia Pacific Forum, The United Nations Declaration on the Rights of Indigenous Peoples, "A Manual for National Human Rights Institutions," <https://www.ohchr.org/documents/issues/peoples/undripmanualforhris.pdf>

⁵¹ Indigenous Peoples Indigenous Voices "Frequently Asked Questions," <https://www.un.org/esa/socdev/unpfii/documents/FAQsindigenousdeclaration.pdf>

⁵² CBD Secretariat of the Convention on Biological Diversity, "Bonn Guidelines on access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization," Available at <https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf>

⁵³ Convention on biological Diversity: ABS, "The Bonn Guidelines". Available at <https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf>

⁵⁴ The Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," Available at <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

5.1.5 Singapore Statement on Research Integrity ('Singapore Statement')

The Singapore Statement promotes four principles which are: honesty, accountability, professional courtesy and fairness, and good stewardship. These are coupled with fourteen responsibilities of ethical conduct on research. The Singapore Statement is not regulatory nor has it been enacted in any country but it encourages the development of consistent and amalgamated policies, procedures, guidelines, codes of conduct to encourage research integrity.⁵⁵ This Statement is applicable to anyone conducting research in any form globally.

5.1.6 Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (Montreal Statement) 2013⁵⁶

The Montreal Statement is not regulatory but addresses cross-boundary research collaborations and the responsibilities of individuals and institutional partners to the research collaboration.

5.1.7 African Union Strategic Guidelines for Coordinated Implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilizations (2015)

The AU Strategic Guidelines "is to provide strategic policy guidance to support the implementation of the NP in Africa and serves as a basis for the development and regular updating of Practical Guidelines with a view to facilitate and ensure coordination and cooperation in the implementation of the Nagoya Protocol in Africa."⁵⁷ It encourages African countries to become parties to the NP and then to adhere to and implement the ABS Strategic Guidelines at a national level in their countries.

5.2 SADC regional legislation, regulations, strategies and / or guidelines for different discipline-specific research

The implementation of the principles of NP to different disciplines of research and other research activities may vary from country to country in the SADC region depending on what legislation, regulations, policies, protocols are in place. Researchers and/or research institutions should consider the legislation, regulations, policies in their own country and other SADC regional countries to enrich

⁵⁵ World Conferences on Research Integrity, "Singapore Statement on Research Integrity" Available at <https://wcrif.org/guidance/>

⁵⁶ The Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations. Available at <https://wcrif.org/montreal-statement/file#:~:text=The%20Montreal%20Statement%20on%20Research,the%20responsible%20conduct%20of%20research>

⁵⁷ African Union Commission. 2015. "African Union Practical Guidelines for Coordinated Implementation of the Nagoya Protocol in Africa" Ethiopia. p5

their knowledge and understanding of the Nagoya Protocol and the ethics guidelines in its application thereto. The following is a neither exhaustive nor fully completed list of legislation, regulations, policies, protocols, but it provides a guideline of what exists in countries that conduct research in specific disciplines. In some countries, there is no national-scale legislation yet in place, but in other SADC countries, it is established and implemented.

5.2.1 Human research – Personal information / Privacy laws

Generally speaking, each SADC country should have stipulated norms and standards for research involving human participants. This research can only be conducted once full ethics approval has been provided by a Research Ethics Committee. The rights, welfare and wellbeing of human participants must be upheld by a researcher at a high level.

There are several elements that a researcher, research institution and/or government would need to consider when conducting research with human participants. One of the most important is the protection of personal information that a researcher may collect and process.

Numerous countries that have protection and the processing of personal information legislation and/or privacy law in place. For example, in South Africa, the Protection of Personal Information Act No. 4 of 2013 (“POPIA”) which is based on the European Union’s General Data Protection Regulation 2016/679 (“GDPR”) relates to the protection and the processing of personal information. This is true for researchers conducting research with human participants and/or where researchers collect personal information from databases of human participants. In Section 12 of the South African Constitution (“Constitution”) it provides for the right to all “to bodily and psychological integrity, which includes the right not to be subjected to medical or scientific experiments without their informed consent.”⁵⁸

Human participants are further protected where a researcher obtains informed consent from the human participants which consent needs to be expressed consent from the human participant. This is in terms of the South African National Health Act⁵⁹ and the South African 2015 DoH Guidelines.⁶⁰ These 2015 Guidelines are more prescriptive in that they provide guidelines as to research conducted with human participants.

⁵⁸ Constitution of the Republic of South Africa, Act No. 106 of 1996

⁵⁹ National Health Act No. 61 of 2003

⁶⁰ Department of Health, Republic of South Africa, 2015. “Ethics in Health Research: Principles, Processes and Structures”

The following are relevant resources to be considered by a researcher in the SADC region conducting human research:

- 5.2.1.1 Belmont Report,⁶¹
- 5.2.1.2 Europe's General Data Protection Regulations – GDPR,
- 5.2.1.3 Angola – Data Protection Law (Law no. 22/11 of 17 June), Electronic Communications and Information Society Services Law (Law no. 23/11, of 20 June 2011) and Protection of Information Systems and Networks Law (Law no. 7/17, of 16 February),
- 5.2.1.4 eSwatini – Data Protection Bill No. 21/2017, Data Protection Act 2017,
- 5.2.1.5 Lesotho – Data Protection Act, 2013, Constitution of the Kingdom of Lesotho, Lesotho ICT Policy 2005,
- 5.2.1.6 Madagascar – Law No. 2014 - 038 on the Protection of Personal Data,
- 5.2.1.7 Namibia – Constitution of the Republic of Namibia, Privacy Act of 1974.

5.2.2 Health research

Health research involving human participants extends into the social science and humanities, which may have health implications. In South Africa, the National Health Act provides statutory authority for governance of health research and the necessary research ethics regulatory infrastructure. The definition of health research can be interpreted widely or with a narrow meaning. Researchers in the humanities and social and behavioural sciences, may find the statutory definition of 'health research' to favour biomedical research. In particular, they may recognize that the so-called 'medical model' for ethics review controls and is applied regularly but improperly to social science, especially qualitative research. Therefore, in a narrow interpretation health research refers to research in a health care environment with patients either in a hospital, clinical or home-based environment. A broad interpretation is when the health research is conducted outside such health care environment without any patients being involved.⁶²

The following are resources to be considered by a researcher in the SADC region conducting health research:

⁶¹ The Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

⁶² Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures" p8

- 5.2.2.1 Republic of Namibia National Health Act 2 of 2015,⁶³
- 5.2.2.2 The South African Medical Research Council Guidelines on the Responsible Conduct of Research 2018,⁶⁴
- 5.2.2.3 National Assembly of Zambia, National Health Research Act No. 2 of 2013,⁶⁵
- 5.2.2.4 Botswana, Guideline for Regulating the Conduct of Clinical Trials Using Medicines in Human Participants 2012,⁶⁶
- 5.2.2.5 Government of Lesotho, Lesotho Health Policy 2011,⁶⁷
- 5.2.2.6 Mauritius Clinical Trials Act No. 8 of 2011,⁶⁸
- 5.2.2.7 Ministry of Health Republic of Seychelles – Act 13 of 2015 Public Health Act, Act 7 of 2013 Public Health Authority Act (gazette 28th October 2013),⁶⁹
- 5.2.2.8 Tanzania National Health Research Forum Guidelines of Ethics for Health Research in Tanzania 2009,⁷⁰
- 5.2.2.9 Zambia National Health Research Act No. 2 of 2013,⁷¹
- 5.2.2.10 Medicines Control Authority of Zimbabwe, Guidelines for Good Clinical Trial Practice in Zimbabwe 2020.⁷²

5.2.3 Indigenous Knowledge Systems

The Protection, Promotion, Development and Management of Indigenous Knowledge Act No. 6 of 2019⁷³ in South Africa affords for the protection, promotion, development and management of indigenous knowledge. The National Indigenous Knowledge Systems Office of South Africa has been established to regulate the Act. The Act contains knowledge of natural resources and their functions, and indigenous cultural expressions. The Act regulates access and benefits-sharing (ABS), commercialisation of indigenous knowledge and recognises indigenous knowledge under intellectual property laws. Indigenous knowledge must be registered with the Registration Office in order to be protected.

⁶³ Available at <https://www.lac.org.na/laws/annoSTAT/National%20Health%20Act%202%20of%202015.pdf>

⁶⁴ Available at <https://www.samrc.ac.za/sites/default/files/attachments/2018-06-27/ResponsibleConductResearchGuidelines.pdf>

⁶⁵ Available at <https://zambialaws.com/principal-legislation/national-health-research-act>

⁶⁶ Available at https://www.who.int/medicines/areas/coordination/zambia_clinical_trials.pdf

⁶⁷ Available at https://extranet.who.int/countryplanningcycles/sites/default/files/planning_cycle_repository/lesotho/health_sector_policy_2011-22_2_3.pdf

⁶⁸ Available at <https://docplayer.net/10802009-Clinical-research-in-mauritius.html>

⁶⁹ Available at <http://www.health.gov.sc/index.php/health-care-laws/>

⁷⁰ Available at <https://clinregs.niaid.nih.gov/sites/default/files/documents/tanzania/G-EthicsHR.pdf>

⁷¹ Available at <https://zambialii.org/node/10700>

⁷² Available at <https://www.mcaz.co.zw/index.php/downloads/category/15-guidelines?download=311:guidelines-for-good-clinical-trial-practice-in-zimbabwe>

⁷³ Available at <http://extwprlegs1.fao.org/docs/pdf/saf192229.pdf>

Indigenous Knowledge may have various definitions but the one that is mostly used in the SADC region is the one that states that it is “knowledge which has been developed within an indigenous community and has been assimilated into the cultural and social identity of that community, and includes (a) knowledge of a functional nature; (b) knowledge of natural resources; and (c) indigenous cultural expressions.”⁷⁴ The Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore (2010)⁷⁵ also discusses the meaning and definitions of Indigenous Knowledge in a SADC context.

Genetic research⁷⁶ is the study of human gene (DNA), heredity and variation and how it affects inheritance of traits and conditions between generations of humans, especially regarding human health and disease. Most SADC countries (10 of 13) indicate that procedures exist for benefit sharing to take place. The operationalisation of national laws and regulatory frameworks found in countries like Democratic Republic of Congo, Malawi, South Africa, Zambia or development of MOUs in the case of Angola, are the common way of proceeding. The involvement of stakeholders and especially indigenous communities as found in eSwatini, Namibia, South Africa are vital to the process, and how monetary benefits are to be shared as seen in Mozambique. The reasons for some countries not having benefit sharing procedures in place yet are due to numerous things, including the lack of capacity, and lack of development of a legislative framework as found in Botswana, Comoros, and Lesotho. The minority of SADC countries (6 of 13) have legislative measures for accessing genetic resources that are compliant with the NP. Those that do so have issues to do with capacity building in their capability to provide service support as found in Angola or the absence of monitoring systems in place as in Malawi.

External support from the GIZ was received by Namibia to develop projects on ABS issues. For those countries without such legislative measures in place, the commonly cited reasons include lack of capacity or enforcement measures as found in the Democratic Republic of Congo, and Lesotho. However, most SADC countries are developing similar frameworks, including Botswana, Lesotho, and South Africa or identified the need for such developments in the Comoros and Mozambique. The lack of strategies for engaging with traditional knowledge systems with 8 of 13 SADC countries indicating they do not have such strategies in place. A legislative framework for managing such traditional knowledge systems exists in several countries, including Namibia, but several countries indicate that

⁷⁴ Protection, Promotion, Development and Management of Indigenous Knowledge Act No. 1082 of 2019 s1

⁷⁵ Available at https://www.wipo.int/edocs/lexdocs/treaties/en/ap010/trt_ap010.pdf

⁷⁶ Department of Health, Republic of South Africa, 2015. “Ethics in Health Research: Principles, Processes and Structures” p32

they do not have such legislation in place like Malawi or have not yet linked such frameworks to the requirements of the NP as in the Democratic Republic of Congo, eSwatini, and South Africa. In terms of compliance, most SADC countries have certain mechanisms to create mutually agreed terms, resolve disputes (11 of 13), and promote such compliance (9 of 13). Several studies mentioned specific legislative instruments or MOUs to enforce these, as is the case in Angola and Lesotho, or that legislation is currently being updated in the Comoros and South Africa.

Twelve SADC countries have the presence of indigenous communities. These indigenous communities can grant access to genetic resources based on a statutory framework in 9 of the 13 SADC countries. Informed consent is provided in most situations, but some countries like the Comoros and Malawi are still developing guidelines for this element. The involvement of indigenous knowledge authorities in developing informed consent is noted in some countries but other countries are still developing this framework, such as the Comoros, Lesotho, Malawi, and Mozambique. Most SADC countries take into consideration indigenous knowledge and customary systems but the context and detail of this differs. In some instances, this is based on training of local indigenous customs and systems as is the case in Lesotho, including communicating with traditional leaders in an informal way which is practiced in Lesotho, Mozambique and South Africa. In many cases, there is a lack of formal structures for engaging with local authorities which is seen in Angola and Madagascar. Several countries, including Botswana and Seychelles do not consider the role of indigenous communities. Relationships can be developed through community-based protocols (9 of 13), agreement of mutual terms (7 of 13) and specification in contracts (7 of 13). Thus, these relationships can be formalised in different ways. Several SADC countries including eSwatini, Malawi and Mozambique indicated the need for clearer definitions of indigenous resources and knowledge systems. Although specific national legislation does exist in several countries like the Democratic Republic of Congo, Namibia, South Africa, and Zambia there is a general absence in other SADC countries.

The Constitution of Zimbabwe is relevant under this context as it deals with the general principles of ABS. For example, Section 33 mandates the State to “take measures to preserve, protect indigenous knowledge systems, including knowledge of the medicinal and other properties of animal and plant life possessed by local communities and people.” Section 13(4) also provides that “the State must ensure that local communities benefit from the resources in their areas”.

The following are some documents to be considered by a researcher whilst conducting indigenous research:

- 5.2.3.1 United Nations Declaration on the Rights of Indigenous Peoples (2007) which talks about the role of customary laws and the importance of self-determination, but not about the nature of data-sharing or its legal implications (including ABS and intellectual property [IP]),
- 5.2.3.2 African Union Strategic Guidelines for Coordinated Implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilizations Protocol 2015,
- 5.2.3.3 Protection, Promotion, Development and Management of Indigenous Knowledge Act No. 1082 of 2019,
- 5.2.3.4 South Africa's National Environmental Management: Biodiversity Act No. 10 of 2004,
- 5.2.3.5 Bioprospecting, Access and Benefit Sharing Regulations 2008;
- 5.2.3.6 Namibia's Access to Biological and Genetic Resources and Associated Traditional Knowledge Bill 2017;⁷⁷
- 5.2.3.7 Zimbabwe's Environmental Management (Access to Genetic Resources and Indigenous Genetic Resource-based Knowledge) Regulations, 2009.⁷⁸

5.2.4 Animal research

Animal research (Moher et al., 2016) is the use of animals as per the South African 2015 DoH Guidelines.⁷⁹ Animal Research includes health research.⁸⁰ In order for a researcher, research institutions and/or a government to conducted health research using animals, they must either have access to or must establish an Animal Research Ethics Committee (AREC) as set out under the South African National Health Act⁸¹ and South African 2015 DoH Guidelines.⁸²

As in each SADC country, there is a Bureau of Standards⁸³ or equivalent (the Seychelles Bureau of Standards) which provides the minimum benchmark to ensure ethical and humane care of animals utilized for scientific and research purposes including teaching activities, consistent with the

⁷⁷ Available at <https://naturaljustice.org/namibia-passes-national-bill-abs-traditional-knowledge/> and <https://www.lac.org.na/laws/annoSTAT/Access%20to%20Biological%20and%20Genetic%20Resources%20and%20Associated%20Traditional%20Knowledge%20Act%20of%202017.pdf>

⁷⁸ Available at <https://absch.cbd.int/en/database/record/ABSCH-MSR-ZW-246489/3>

⁷⁹ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures" p10 and the National Health Act No. 61 of 2003 at s73(6)(c)

⁸⁰ SANS 10386:2008

⁸¹ National Health Act No. 61 of 2003 at s73(1)

⁸² Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures" p10 and p40

⁸³ South African Bureau of Standards SANS 10386:2008

fundamental principles of Replace, Reduce and Refine animal use (the 3R Rule). One of the main considerations with animal research reviews is to protect the safety and welfare of such animals being utilised for animal research by ensuring that the researchers follow the stipulated standards. Researchers, research institutions and governments are to familiarise themselves with the content of the Bureau of Standards minimum requirements as well as the equivalent of the South African 2015 DoH Guidelines as necessary.

International and foreign resources to be considered by a researcher when conducting animal research are as follows:

- 5.2.4.1 World Organization for Animal Health Guidelines (OIE),⁸⁴
- 5.2.4.2 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes,
- 5.2.4.3 World Organization for Animal Health, Terrestrial Animal Health Code for the Use of Animals in Research and Education 2019,
- 5.2.4.4 Council for International Organizations Biomedical Research involving Animals, International Guiding Principles for Biomedical Research Involving Animals 1985 (CIOMS),
- 5.2.4.5 Guide for the Care and Use of Laboratory Animals, produced by the Institute for Laboratory Animal Research 2010 (ILAR Guide),
- 5.2.4.6 Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition) 2013,
- 5.2.4.7 Zambia Wildlife Act No. 14 of 2015⁸⁵ - deals with trade in wild animals and their meat,
- 5.2.4.8 Mauritius Animal Welfare Act of 2013,
- 5.2.4.9 Zambia Biosafety Act No. 10 of 2007⁸⁶ provides rules for the import/export, research and release of genetically modified organisms,
- 5.2.4.10 Zambia's Plant Breeder's Rights Act No. 18 of 2007⁸⁷ This Act is in relation plant breeders' intellectual property rights and registration status, the storage of genetic materials in a resource centre or herbarium, and rules for genetically modified seeds,

⁸⁴ Available at <https://www.oie.int/en/what-we-do/standards/>

⁸⁵ Available at <http://extwprlegs1.fao.org/docs/pdf/zam163735.pdf>

⁸⁶ Available at <http://extwprlegs1.fao.org/docs/pdf/zam78318.pdf>

⁸⁷ Available at <http://extwprlegs1.fao.org/docs/pdf/zam78315.pdf>

- 5.2.4.11 Zambia Environmental Management Act No. 12 of 2011⁸⁸ provides for in-situ and ex-situ conservation of biological diversity,
- 5.2.4.12 South African Bureau of Standards SANS 10386:2008,
- 5.2.4.13 South African Medical Research Council Guidelines on Ethics for Medical Research: Use of Animals in Research and Training (2004),
- 5.2.4.14 Seychelles Animal and Plant Biosecurity Act No. 10 of 2014,⁸⁹
- 5.2.4.15 Constitution of Zimbabwe Act No. 20 of 2013 (as amended),⁹⁰
- 5.2.4.16 South African Animal Diseases Act 35 of 1984,
- 5.2.4.17 South African Animal Health Act 7 of 2002,
- 5.2.4.18 South African Animals Protection Act 71 of 1962,
- 5.2.4.19 South African Performing Animals Protection Act 24 of 1935,
- 5.2.4.20 South African Provincial Nature Conservation Acts or Ordinances,
- 5.2.4.21 South African Rules Relating to the Practising of the Para-Veterinary Profession of Laboratory Animal Technologist (1997),
- 5.2.4.22 South African Department of Agriculture (1997) GN 1445 of 3 October 1997,
- 5.2.4.23 South African Rules Relating to the Practising of the Profession of Veterinary Nurse. Department of Agriculture (1991) GN 1065 of 17 May 1991,
- 5.2.4.24 South African Societies for the Prevention of Cruelty to Animals Act 169 of 1993,
- 5.2.4.25 South African Sterilization Act 44 of 1998,
- 5.2.4.26 South African Veterinary and Para-veterinary Professions Act 19 of 1982.

5.2.5 Biodiversity and conservation⁹¹

The SADC region has abundant biodiversity with well-developed indigenous knowledge coupled with high vulnerabilities due to poverty, language and literacy issues. This indicates that there is a coincidence between areas where genetic and biological resources may be exploited, and where communities vulnerable to this exploitation are found. The International Work Group for Indigenous Affairs (IWGIA)⁹² have indicated that several SADC countries such as Angola, Comoros, eSwatini, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Seychelles, and Zambia are missing due to a lack of information. Thus, the status of human rights and other issues related to indigenous communities in these areas is unknown. The legislative framework around biodiversity, conversation

⁸⁸ Available at <http://extwprlegs1.fao.org/docs/pdf/zam117523.pdf>

⁸⁹ Available at <http://extwprlegs1.fao.org/docs/pdf/sey143899.pdf>

⁹⁰ Available at <http://extwprlegs1.fao.org/docs/pdf/zim127325.pdf>

⁹¹ Southern African Development Community, Regional Biodiversity Strategy 2008, Available at https://www.sadc.int/files/1213/5293/3516/SADC_Regional_Biodiversity_Strategy.pdf

⁹² Available at <https://iwgia.org/en/>

and biological resources vary from country to country in the SADC region as some do not have national-scale legislation but elements of ecological resource and biodiversity conservation are included in other measures.

Legislative instruments and policies can be found in the SADC region which discuss the sustainable use of indigenous biological resources and ABS arising from bioprospecting.⁹³ NP Regulations implementing the legislation on Bio-Prospecting, Access and Benefit-Sharing and these provide rules for bioprospecting and the commercialization of indigenous biological resources, this includes criteria for ABS and MAT. Permits are another legal instrument that has been implemented to provide for bio trading and bioprospecting.

One legal instrument used to regulate any biological resources and materials to be transferred to another party must be a material transfer agreement or a data transfer agreement that the parties must enter into. Another instrument is an access and benefit sharing agreement which allows a party access to the biological material for example and to allow them to commercialize the biological material for example, but then for the indigenous community to benefit in the exploitation of such resources. This is discussed in more detail in the Toolkit section of these Guidelines.

The following are some documents to be considered by a researcher whilst conducting research on Biodiversity and Conservation:

- 5.2.5.1 The United Nations Convention on Biological Diversity 1993 (CBD) (as updated),⁹⁴
- 5.2.5.2 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity 2011,⁹⁵
- 5.2.5.3 Cartagena Protocol on Biosafety to the Convention on Biological Diversity 2000,
- 5.2.5.4 UN Global Declaration on Human Rights of Indigenous People 2007,⁹⁶

⁹³ National Environmental Management Biodiversity Act No. 10 of 2004, Available at <http://extwprlegs1.fao.org/docs/pdf/saf45083.pdf>

⁹⁴ United Nations LDC Portal International Support Measures for Least Developed Countries, "Convention on Biological Diversity (CBD) and Protocols," Available at <https://www.un.org/ldcportal/convention-on-biological-diversity-cbd/>

⁹⁵ United Nations, "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity". Available at <https://www.cbd.int/abs/about/#importance>

⁹⁶ United Nations Human Rights and Asia Pacific Forum, The United Nations Declaration on the Rights of Indigenous Peoples, "A Manual for National Human Rights Institutions," Available at <https://www.ohchr.org/documents/issues/ipeoples/undripmanualfornhri.pdf>

- 5.2.5.5 African Union Strategic Guidelines for Coordinated Implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilizations Protocol 2015,
- 5.2.5.6 Southern African Development Community 2008, Regional Biodiversity Strategy,
- 5.2.5.7 Angola's National Biodiversity Strategy and Action Plan (2019-2025), approved in February 2020 - deals with different industrial sectors and regions. Progress towards achieving the Aichi biodiversity goals (2011-2020),
- 5.2.5.8 Angola's Law No. 5/21, the Plant Health Act (February 2021) - protection of agricultural and forestry production and exploitation, and the trade and import of these plants and products. It includes monitoring and inspection of interprovincial and international trade of plants and their products, development of inspection control rules and procedures, and powers to inspect, supervise and take action against offenders,
- 5.2.5.9 Angola's Law No. 6/17 on Forest and Wildlife Basic Legislation (2017) applies to biological diversity and related activities, but does not apply to aquatic biological resources, genetic resources and conservation areas that are governed by special legislation,
- 5.2.5.10 South Africa's Biodiversity Act No. 10 of 2004,
- 5.2.5.11 South Africa's National Environmental Management: Biodiversity Act 10 of 2004 (NEMBA),
- 5.2.5.12 South Africa's Indigenous Biological Resources Act No. 10 of 2004,
- 5.2.5.13 South Africa's Plant Health (Phytosanitary) Policy (2014),
- 5.2.5.14 South Africa's Plant Breeders' Rights Act No. 12 of 2018,
- 5.2.5.15 South Africa's Protection, Promotion, Development and Management of Indigenous Knowledge Act No. 6 of 2019,
- 5.2.5.16 South Africa's 2nd National Biodiversity Strategy and Action Plan (2015),
- 5.2.5.17 Botswana's National Biodiversity Strategy and Action Plan (2016),
- 5.2.5.18 Democratic Republic of Congo national biodiversity action plan Strategie et Plan d'Action Nationaux de la Biodiversité⁹⁷ (SPANB),
- 5.2.5.19 Swaziland's Second National Biodiversity Strategy and Action Plan (2016),⁹⁸
- 5.2.5.20 Lesotho National Biodiversity Strategy and Action Plan (2000),⁹⁹
- 5.2.5.21 Lesotho Environment Act 2008,

⁹⁷ Available at <http://extwprlegs1.fao.org/docs/pdf/Cng169379.pdf>

⁹⁸ Available at <http://extwprlegs1.fao.org/docs/pdf/swa170338.pdf>

⁹⁹ Available at <https://www.cbd.int/doc/world/ls/ls-nbsap-01-en.pdf>

5.2.5.22 Madagascar National Biodiversity Strategy and Action Plans (2015-2025),¹⁰⁰

5.2.5.23 Malawi National Biodiversity Strategy and Action Plan II (2015–2025),¹⁰¹

5.2.5.24 Namibia Environmental Management Act (No. 7 of 2007),¹⁰²

5.2.5.25 Environment Protection and Biodiversity Conservation Act 1999.¹⁰³

5.2.6 Genetic and genomic research

Genetic research¹⁰⁴ is the study of human gene (DNA), heredity and variation and how it affects inheritance of traits and conditions between generations of humans, especially regarding human health and disease. A gene is the unit of heredity. Genetic research can be beneficial but has its dangers or negative impacts. Genetic research is to explore the causes of diseases and how these can be prevented or solved. Genetic research may have negative implications on the human participants taking part in this research. These may vary from unfair discrimination, stigmatization and many other effects. Genomic research¹⁰⁵ is the study of a person's genome (i.e. genes) and how these communicate with each other and with one's environment. This research allows for exploration into diseases at a population level to take into account not only genetic, but also environmental factors.

The Nagoya Protocol allows for access to genetic resources in a fair and equitable way in order for the parties involved to be able to share the benefits arising from the utilization of the genetic resources. Many SADC countries have benefit-sharing mechanisms in place but occasionally these are without the national legislative framework to legally guide such activities. In order for this concept to work effectively there needs to be a sharing of best practices of legislative and management framework between SADC countries in order for there to be consistency.

In terms of equitable benefit sharing, most SADC countries indicate that procedures exist in order for this to take place. The most common ways in which this has been done is through the operationalisation of national laws and regulatory frameworks as found in the Democratic Republic of Congo, Malawi, South Africa, and Zambia or development of MOUs as utilized in Angola.

¹⁰⁰ Available at <https://www.cbd.int/doc/world/mg/mg-nbsap-v2-en.pdf>

¹⁰¹ Available at <https://www.cbd.int/doc/world/mw/mw-nbsap-v2-en.pdf>

¹⁰² Available at <http://extwprlegs1.fao.org/docs/pdf/nam82643.pdf>

¹⁰³ Available at http://extwprlegs1.fao.org/docs/pdf/aus17072_Volume1.pdf

¹⁰⁴ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures" p32

¹⁰⁵ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures" p32

For example in Zambia there are several laws dealing with genetic and biological resources, but several that are listed in the Interim National Report are just not relevant to this topic. The main law of direct relevance is the Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act No. 16 of 2016.¹⁰⁶

The genetic and genomic following are some documents to be considered by a researcher whilst conducting research on Biodiversity and Conservation:

- 5.2.6.1 International Treaty on Plant Genetic Resources for Food and Agriculture 2009,
- 5.2.6.2 African Union Strategic Guidelines for Coordinated Implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilizations Protocol 2015,
- 5.2.6.3 SADC Plant Genetic Resources Network,¹⁰⁷
- 5.2.6.4 Angola Law No. 5/21, the Plant Health Act (February 2021),¹⁰⁸
- 5.2.6.5 Democratic Republic of Congo Conservation of Nature law (2014) (Loi n°14/003 du 11 février relative à la Conservation de la Nature,¹⁰⁹
- 5.2.6.6 Malawi - The Environmental Management Act of 2017,¹¹⁰
- 5.2.6.7 Malawi National Seed Policy 2018,¹¹¹
- 5.2.6.8 Malawi - The Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002), revised editions 2015,¹¹²
- 5.2.6.9 Malawi - The Biosafety Act (Cap. 60:03) (2007),¹¹³
- 5.2.6.10 Namibia Access to Biological and Genetic Resources and Associated Traditional Knowledge Act (No. 2 of 2017),¹¹⁴
- 5.2.6.11 Namibia Biosafety Act (No. 7 of 2006),¹¹⁵
- 5.2.6.12 Namibia Environmental Management Act (No. 7 of 2007),¹¹⁶
- 5.2.6.13 Seychelles Animal and Plant Biosecurity Act 2014 (No. 10 of 2014),¹¹⁷

¹⁰⁶ Available at <http://extwprlegs1.fao.org/docs/pdf/zam163186.pdf>

¹⁰⁷ Available at <https://www.spgrc.org.zm/>

¹⁰⁸ Available at <http://www.fao.org/faolex/results/details/en/c/LEX-FAOC200589>

¹⁰⁹ Available at <https://www.leganet.cd/Legislation/Droit%20administratif/Environnement/Loi14003.11.02.2014.htm>

¹¹⁰ Available at <http://extwprlegs1.fao.org/docs/pdf/mlw169354.pdf>

¹¹¹ Available at <http://extwprlegs1.fao.org/docs/pdf/mlw180417.pdf>

¹¹² Available at <https://www.ncst.mw/wp-content/uploads/2020/01/REVISED-Procedures-and-Guidelines-for-Access-and-Collection-of-Genetic-Resources-in-Malawi.pdf>

¹¹³ Available at <http://extwprlegs1.fao.org/docs/pdf/mlw117644.pdf>

¹¹⁴ Available at <http://extwprlegs1.fao.org/docs/pdf/nam173079.pdf>

¹¹⁵ Available at <http://extwprlegs1.fao.org/docs/pdf/nam126357.pdf>

¹¹⁶ Available at <http://extwprlegs1.fao.org/docs/pdf/nam82643.pdf>

¹¹⁷ Available at <http://extwprlegs1.fao.org/docs/pdf/sev143899.pdf>

- ### 5.2.7 Community engaged research

The CBD and NP do not offer any clarification nor a definition for the term “Indigenous Community.” But in terms of the NP it is generally understood to encompass communities living close to nature and holding genetic resources and indigenous knowledge associated with the genetic resource.¹²⁰

¹¹⁸ Available at <https://naturaljustice.org/namibia-passes-national-bill-abs-traditional-knowledge/> and <https://www.lac.org.na/laws/annoSTAT/Access%20to%20Biological%20and%20Genetic%20Resources%20and%20Associated%20Traditional%20Knowledge%20Act%202020of%202017.pdf>

¹²⁰ Glossary of key Terms Used in the Context of “Access and Benefit-Sharing” Available at [European Commission, official website \(europa.eu\)](https://ec.europa.eu/eip/eip/eip_glossary.htm)

an ongoing process in order to sustain the respect that is so required which can be done through recognized community leadership and/or community structures (Kruger et al., 2014).

In conducting research within a specific community, knowledge will be produced which should benefit the researcher and the community respectively. The researcher will need to ensure that the community members that will partake in the research are not vulnerable and are protected from any harm and/or risk that may arise. Researchers will need to identify the relevant indigenous community and research participants from that specific community that the researcher will engage with to participate in the specific research project.¹²¹ The researcher will need to follow for example, South Africa's 2015 DoH Guidelines or equivalent in the country where the research is being conducted as these set out the necessary measures that need to be put in place for prevention and the minimization of risks and any harm that may arise and which needs to be documented correctly. The researcher will need to identify any other negative impacts that may arise during the participation of community members.

Researchers must contemplate how the selection of certain research participants will assist them in achieving their research goals. It is recognised in community research that some stakeholders may drop out and others may join the research. The same ethical reflections must apply to all participants who form part of the collaborative research initiative. A researcher must not discriminate in the selection and/or recruitment of actual or prospective participants by including or excluding them on the grounds of race, age, sex, disability, or religious or spiritual beliefs or any other discriminatory grounds except where these criteria is essential to the purpose of the research.¹²²

The researcher will need to consider and identify how the research participants will benefit from the research. The researcher may additionally consider how the outcomes or deliverables of the research could have wider applicability. The researcher with the assistance of the specific community will identify beneficiaries which ought to be directly involved in the research. The beneficiaries' involvement in the research must be cautiously considered by the researcher as to how and when the beneficiary should be involved.

The researcher will need to be flexible in their approach in considering participants' social and economic circumstances for example, or the necessity for participants to have child care for their

¹²¹ UNISA 2016. "Policy on Research Ethics." p 41-45

¹²² UNISA 2016. "Policy on Research Ethics." p 41-45

children whilst they partake in the research, and this may require the research to schedule the interaction around the availability of the participants, or the cost of transport for participants to be at research sites. The participants and the community should be realistic about times, involvement and resources constraints that they may or will be experiencing.¹²³

Community-engaged research is vital for the implementation of the NP as indigenous communities are key stakeholders as they potentially hold the indigenous knowledge of the genetic and/or biological materials in their environment. Therefore, it is vital for researchers, research institutions and government to build a relationship of respect, trust, honesty, justice and fairness, and care with such communities in order for them to feel that they are not being exploited in anyway. These four principles of research conduct of research conducted within a community setting is found in the San Code of Research Ethics 2017.¹²⁴ These are briefly described as follows:¹²⁵

- Respect: When a researcher is engaging with the specific community which has been identified to take part in the research, then the researcher should be respectful to the individual members of the community, the community, community structures, local culture, customs and the research contributions of the participants and the community,
- Honesty: A researcher must endeavour to promote honesty and sharing of information throughout the life cycle of the research project with the community leaders and participants;
- Justice and fairness: This is where the community leaders/leadership and participants must partake in a meaningful way to the proposed project which includes for the researcher to be informed about the benefits that the participants and the community may expect, and
- Care: The researcher must familiarize themselves with the local needs of the community and to improve the lives of the community either during and/or after the research has been completed.

A researcher may engage with the community via three different scenarios namely (Kruger et al., 2014):

1. Consultation with the Community: The researcher will need to initiate engagement with the specific community first and then proceed to engage the community to encourage a

¹²³ UNISA 2016. "Policy on Research Ethics." p 41-45

¹²⁴ SAN Code of Research Ethics. 2017. TRUST. Available at <http://trust-project.eu/wp-content/uploads/2017/03/San-Code-of-RESEARCH-Ethics-Booklet-final.pdf>

¹²⁵ UNISA 2016. "Policy on Research Ethics." p 42

relationship of communication. The earlier that a community is engaged the more the benefit to the researcher as then the researcher will receive the community's input (i.e. indigenous knowledge) from the start of the process. There are certain environmental factors that will impact on the outcomes of the research such as decision making by the community, stigmatization, power dynamics, cultural structure etc,

2. Collaboration with the Community: This is the level of engagement where there needs to be a legitimate political authority to be established such as chiefs, tribal councils, etc and government backed development and health-related community-based organisations that make choices for the community. If these structures are not in place then other community stakeholders will need to be engaged. This engagement must be inclusive and for community members not to be excluded from the process as valuable knowledge and inputs will potentially be lost. Community leaders and structures will need to approve the research and provide guidance on how to engage with which members of the community. The main element in this level of engagement is for the researcher to identify the appropriate stakeholders to consult with in the community in order to gain informed consent and to request advice during the research be implemented, and
3. Partnership with the Community: This level of engagement is where the researcher will consider the community members as partners in identifying challenges in the health sector for example, which allows the researcher to explore the potential of solutions to challenges faced in the community.

Community-engaged research is unambiguously value-driven in that the process of conducting research can focus on the emancipation of a variety of vulnerable, exploited or oppressed groups. The risks that participants may face during the research need to be comparable to the potential benefits to the individual participants or to the community generally. The researcher will need to consider these risks and more potential risks that may arise during the research. The researcher needs to illustrate how they will go about sensitizing themselves to the culture and politics of the community. The researcher conducting the community engaged research needs to consider the impact of power plays within their community which includes politics. The research may result in political consequences which will have to be alleviated by the researcher.

In some SADC countries, government authority permission needs to be attained for the research where necessary. This permission should not be confused with the community leadership and/or authorities. In some cases, it might be vital for the researcher to receive consent from the respected, traditional and/or elected community leaders/leadership. Informed consent in community-based research is required to be received by the community and the participants. This needs to include the complete information about objectives, risks, and adverse impacts on participants whilst they take part in the research.

The roles and responsibilities of the participants and the community stakeholders need to be provided up front before the commencement of the research. The distortion of participant and researcher roles and responsibilities will require special precautions for the safeguard of confidentiality. The researcher will need procedures to be in place in order to safeguard the information provided by the participants and the community. Researchers must provide a true and fair depiction of the research and not distort it in anyway. The researcher will need to be cautious in not overestimating the benefits for the participants and the community. The participants will need to be cautioned by the researcher that they must not formulate any responses that may be biased and induce a positive outcome.¹²⁶

The researcher will need to have the necessary agreements executed concerning the interpretation, ownership and access of data, information and intellectual property, authorship and the dissemination of findings and financial accountability. Researchers must negotiate the process and specifics of authorship and co-authorship of the data that was collected during the research but also the dissemination of such data. Researchers must contemplate the potential consequences to the individual participants and / or community if sensitive or not sensitive data is released precipitately or in an insensitive or any other manner.

Community engagement research may lead to a situation of access and benefit sharing which needs to be governed by an ABS agreement so that all parties know their rights and obligations and what the access rights to genetic and/or biological material will be and how and what will benefit of the outcomes. The ABS is set up after negotiations between the community and the researcher, research institution and/or Governments. Mutually Agreed Terms need to be negotiated in terms of the genetic resources and/or indigenous knowledge of the community and the sharing of the benefits resulting from the utilization of the materials and associated knowledge.

¹²⁶ UNISA 2016. "Policy on Research Ethics." p 41-45

An ABS cannot take the place of any legal requirements in any country providing the genetic resources and/or associated indigenous knowledge. The ABS needs to be compliant with any access and benefit sharing legislation and/or regulations that are in place in the country of the provider and the user country.¹²⁷ Material Transfer Agreements (MTAs) and Data Transfer Agreements (DTAs) are other legal instruments that a researcher may use to assist in the negotiations and engagement with Communities. A Non-Disclosure Agreement (NDA) may be utilized at the start of the engagement between the researcher and the community to provide some comfort to the parties that neither party will be able to disclose anything that they discuss. The Toolkit that has been set up for the guidelines herein provide guidance on how the ABS, MTA, DTA and NDA are utilized with the relevant legislation and regulations that may apply.

The following pieces of legislation, regulations, and guidelines present some direction as to where the researcher may start to look at the literature on community engagement research:

- 5.2.7.1 United Nations Convention on Biological Diversity 1993 (CBD),¹²⁸
- 5.2.7.2 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity 2011,¹²⁹
- 5.2.7.3 UN Global Declaration on Human Rights of Indigenous People 2007,¹³⁰
- 5.2.7.4 African Union Strategic Guidelines for Coordinated Implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilizations Protocol 2015,
- 5.7.7.5 ABSCH -The Access and Benefit-Sharing Clearing House,¹³¹
- 5.7.7.6 ABS Information Forum,¹³²
- 5.7.7.7 Swiss Academy of Sciences, Agreement on Access and Benefit Sharing for Non-Commercial Research: Sector Specific Approach Containing Model Clauses,¹³³

¹²⁷ Swiss Academies Reports, "Agreements on access and Benefit-Sharing for Academic Research – A Toolbox for Drafting Mutually Agreed Terms for Access to Genetic Resources and to Associated Traditional Knowledge and Benefit-Sharing," 2016

¹²⁸ Available at <https://www.cbd.int/abs/>

¹²⁹ Available at <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>

¹³⁰ United Nations Human Rights and Asia Pacific Forum, The United Nations Declaration on the Rights of Indigenous Peoples, "A Manual for National Human Rights Institutions," Available at <https://www.ohchr.org/documents/issues/ipeoples/undripmanualforhris.pdf>

¹³¹ Available at <https://absch.cbd.int/>

¹³² Available at <http://nagoyaprotocol.myspecies.info/> and <http://nagoyaprotocol.myspecies.info/node/21>

¹³³ Available at <https://www.cbd.int/abs/doc/model-clauses/noncommresearch-abs-agreement.pdf>

- 5.7.7.8 Access and Benefit Sharing Agreements: Resources and Background Materials,¹³⁴
- 5.7.7.9 African Union Practical Guidelines for Coordinated Implementation of the Nagoya Protocol in Africa 2015,¹³⁵
- 5.7.7.10 National Health Act 2003 No. 61 of 2003 Material Transfer Agreement of Human Biological Materials, Government Gazette 20 July 2018 No. 41781, clause 3.4,¹³⁶
- 5.7.7.11 ABS Information Forum: Tools & Resources - Material Transfer Agreements,¹³⁷
- 5.7.7.12 A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements.¹³⁸

6. GUIDELINES FOR THE IMPLEMENTATION OF RESPONSIBLE AND ETHICAL RESEARCH

6.1 Institutions

Institutional settings in which research is planned and subsequently executed are crucial, both for publicly funded and private research. Institutions are social structures or organizations established a religious, educational, professional or social purpose. In the context of this Guideline, institutions may include research institutions such as a university or government or private laboratory, which is involved in conducting research, the government, publishing companies, funding organizations and the corporate and lobbyists such as animal welfare or Human Rights organizations, industry, non-governmental organizations and consultants.

6.1.1 Governance and leadership

a) Research ethics

Research ethics refers to the responsible conduct of all types of research in all disciplines (Dooly et al., 2017). The abuses of human research participants in the western world have played a significant role in shaping present-day research protection norms, standards and requirements (Kruger et al., 2014). It is the duty or obligation of the research community to follow principled and scientific standards and legal and institutional rules in the conduct of research.¹³⁹ Community representatives and researchers

¹³⁴ Laird, S.L., Virnig, A.L.S., and Wynberg, R. 2018. "Access and Benefit-Sharing Agreements: Resources and Background Materials," Available at <https://www.voices4biojustice.org/wp-content/uploads/2017/12/ABS-Agreements-Packet-LOGO-sml.pdf>

¹³⁵ Available at http://www.biodiversityinternational.org/fileadmin/user_upload/campaigns/Treaty_and_Nagoya_Workshop_2015/AU_Practical_Guidelines_on_ABS-English.pdf

¹³⁶ Available at https://www.gov.za/sites/default/files/gcis_document/201808/41781gon719.pdf

¹³⁷ Available at <http://nagoyaprotocol.myspecies.info/node/3>

¹³⁸ Available at https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf

¹³⁹ Resnik 2020, What Is Ethics in Research & Why Is It Important? Available at [What Is Ethics in Research & Why Is It Important? - by David B. Resnik, J.D., Ph.D. \(nih.gov\)](https://www.nih.gov/ethics/what-is-ethics-in-research-why-is-it-important/)

can work together to ensure that research is conducted in the most appropriate way and to high ethical standards (Rivera et al., 2004).

One of the primary goals of research is to protect research volunteers by incorporating ethical considerations into the research study design and implementation (Rivera et al., 2004). This is expanded by Resnik¹⁴⁰ who outlined several reasons why it is important to adhere to ethical norms in research informed by codified standards. These include to promote the aims of research such as knowledge, truth, and avoidance of error, for example, prohibition of fabrication, falsifying, or misrepresenting research data. Secondly, to promote values essential to collaborative research work such as trust, accountability, mutual respect, and fairness. Thirdly, many of the ethical norms help to ensure that researchers can be held accountable to the public for example policies on research misconduct, conflicts of interest, protection of human subjects, biodiversity protection, animal use and welfare are necessary in order to make sure that researchers funded by public money can be held accountable to the public. Fourth, ethical norms in research help to build public support for research. People are more likely to fund a research project if they can trust the quality and integrity of research and researchers. Lastly, many of the norms of research promote a variety of other important moral and social values, such as social responsibility, human rights, animal welfare, compliance with the law, and public health and safety. As such, a researcher who fabricates data in a clinical trial may harm or even kill patients, and a researcher who fails to abide by regulations and guidelines relating to radiation or biological safety may jeopardize his/her health and safety or the health and safety of staff, students or the general public. Therefore, institutions have a role to play to ensure that research ethics principles are adhered to.

Institutions should have policies and frameworks in place that guide the conduct of researchers. Also, policies to deal with violation of research ethics and integrity must be present and implemented accordingly where necessary. RECs and researchers should be given clear instructions and research ethics support during health emergencies and pandemics like COVID-19.¹⁴¹

Institutions mandate is to ensure that researchers comply with the research ethics principles and protocols before, during and after embarking on a research project to avoid any potential harm to research subjects, bias on selecting research subjects, ensure privacy and confidentiality, and that

¹⁴⁰ Resnik 2020, What Is Ethics in Research & Why Is It Important? Available at [What Is Ethics in Research & Why Is It Important? - by David B. Resnik, J.D., Ph.D. \(nih.gov\)](#)

¹⁴¹ Research Ethics Support in COVID-19 Pandemic (RESCOP): Proposed Rapid Review Process For South African RECs. Available at <https://www.vut.ac.za/wp-content/uploads/2020/04/RESCOP-2020-PROPOSED-RAPID-REVIEW-PROCESS.pdf>

informed consent is signed with respects, honesty and transparency providing room to opt out if necessary, without any prejudice.

b) Research integrity

Research integrity is the performance of research according to the highest standards of professionalism and rigour, in an ethically robust manner.¹⁴² Research integrity encompasses responsibilities for the research community and assurance of society's trust in the outcomes of research.¹⁴³ This implies that researchers report their work honestly, accurately, efficiently and objectively. It also requires them to use honest and verifiable methods in proposing, performing and evaluating research, to report accurate results with respect to rules, to follow commonly accepted professional norms and not allow personal bias to influence scientific findings or the conduct of research process. The credibility of science relies on the quality and reproducibility of results. Research integrity is important because the outcome and interpretation of research can be verified by the scientific community, but cannot be verified by the public or decision makers for whom the new knowledge is intended. Therefore, citizens need to have confidence in researchers. There are core principles and responsibilities of research integrity. These are alluded to in two important international guiding documents; the Singapore Statement on Research Integrity (2010) and the European code of conduct for research integrity (2017). The principles vary with national policies, national cultures and across disciplines. The core principles are honesty, accountability, reliability, professional courtesy and fairness in working with others, good stewardship of research on behalf of others, accuracy, efficiency, objectivity, impartiality and independence, open communication, duty of care fairness and responsibility for future generations of researchers. Research integrity can also be called integrity at scientific research, responsible conduct of research, code of ethics for science, code of practice for research, and good scientific practice. In the context of this guideline, research integrity will be used to mean responsible conduct of research to high standards of ethics, professionalism and rigour.

Research institutions are required to comply with commonly accepted professional codes and norms, and have mechanisms for handling allegations of research misconduct. Institutions should monitor and train researchers and students at various stages of their career on conflict of interest, responsible authorship, data management and sharing, as well as policies regarding the use of human and animal subjects, and biological or genetic materials.

¹⁴² Resnik 2020, What Is Ethics in Research & Why Is It Important? Available at <https://ahrecs.com/resources/ethics-research-important-resources-david-b-resnik-2015/>

¹⁴³ Available at https://www.sisnetwork.eu/media/sisnet/Policy_brief_Research_Integrity_SiSnet.pdf

At national level, the national contact points should actively contribute to maintaining the highest possible standards in research integrity. The national contact point (NCP) should ensure that the local research community is satisfactorily informed about the values of integrity and excellence. They should regularly consult on clients' needs in the area of research integrity, raising awareness of codes of conduct both for researchers and institutions, identify mentors and suggest those to less experienced researchers, support research organisations in providing clear and transparent research integrity policy, understand and identify risks that could lead to misconduct, and know the tools and structures used to report misconduct. For example, the Research Integrity Office (RIO) provides a recommended checklist for researchers on key points of good practice in research for all disciplines. Another example is an international initiative "Think. Check. Attend." that uses a simple survey as a guide for researchers.¹⁴⁴ This helps researchers for instance to judge the legitimacy and academic credentials of conferences they have to attend or to identify trusted and non-predatory journals. It should be noted that responsible research conduct is fostered and underpinned by the research culture of the institution. Additionally, institutions are accountable to funding organisations and their nations for how research is conducted. Therefore, to foster responsible research conduct, institutions should:

- Establish and maintain good governance and management practices for responsible research conduct,
- Identify and comply with relevant laws, regulations, guidelines and policies related to the conduct of research,
- Develop, maintain and readily avail a suite of policies and procedures which ensure that institutional practices are consistent with the principles and responsibilities of the research conduct,
- Identify and train Research Integrity Advisors who promote and foster responsible research conduct and provide advice to those with concerns about potential breaches of the research principles and practices, and
- Support the responsible dissemination of research findings.

6.1.2 Capacity building

It is the mandate of institutions to ensure that their staff is trained in research ethics and integrity and all credible research processes. These include the researchers, students, research community and

¹⁴⁴ Available at <https://allea.org/code-of-conduct/>

research ethics committee members. Thus, institutions should ensure that researchers receive rigorous training in research design, methodologies, data collection and analyses. As such, researchers across the entire career path, from junior to the most senior level, should undertake training in ethics and research integrity. Institutions should develop appropriate and adequate training in ethics and research integrity to ensure that all concerned are made aware of the relevant principles and regulations and make it part of accredited continued professional development. It should be mandatory that senior researchers, research leaders and supervisors mentor their team members and offer specific guidance and training to properly develop, design and structure their research activities and to foster a culture of research integrity. Institutions should ensure that monitored structures are in place for especially providing less experienced researchers with mentorship and coaching opportunities for developmental capacity and upholding research ethics and integrity principles. This is crucial and ensures that training on research ethics and integrity, supervision and necessary mentorship is fostered with institutions for the good of achieving the mandate of conducting research in the respectable realms of ethics and integrity. Institutions are responsible for providing ongoing training and education that promotes and supports responsible research conduct for all researchers and those in other relevant roles. They also have to ensure supervisors of research trainees have the appropriate skills, qualifications and resources to conduct research appropriate to the international standards of their discipline.

6.1.3 Resource mobilisation

Institutions should provide access to facilities for the execution of research and the safe and secure storage and management of research data, records and primary materials and, where possible and appropriate, allow access and reference. This is key for reproducibility, traceability and accountability. Appropriate monitoring and evaluation of the resources is key for accountability purposes.

6.1.4 Work environments that support responsible and ethical research

According to The European Guideline for Research Integrity Revised Edition (2017)¹⁴⁵ and Australian Code for the Responsible Conduct of Research (2018)¹⁴⁶, an enabling environment for undertaking research must prevail. This include provision of infrastructure, capacity and training, framework documents for upholding research ethics and integrity, and other necessary resources for undertaking responsible research to high standards. It is the mandate of research institutions and organisations to foster such a research environment and hence they must promote awareness and ensure a prevailing

¹⁴⁵ Available at <https://allea.org/code-of-conduct/>

¹⁴⁶ Available at <https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>

culture of research integrity. Institutions are also expected to demonstrate leadership in providing clear policies and procedures on good research practice and the transparent and proper handling of violations. Institutions are also expected to:

- Demonstrate leadership in providing clear policies and procedures on good research practice and the transparent and proper handling of violations,
- Reward good performing researchers, open and reproducible practices in hiring and promotion of researchers, and
- Monitor and address underperformance.

6.1.5 Data protection and management

Issue of data management is crucial and this should be a collective action of researchers, institutions and funders. Likewise, these stakeholders must ensure that:

- Appropriate stewardship and curation of all data and research materials, including unpublished ones, with secure preservation for a reasonable period,
- Access to data is as open as possible, as closed as necessary, and where appropriate in line with the FAIR Principles (Findable, Accessible, Interoperable and Re-usable) for data management,
- They provide transparency about how to access or make use of their data and research materials,
- They acknowledge data as legitimate and citable products of research, and
- Any contracts or agreements relating to research outputs include equitable and fair provision for the management of their use, ownership, and/or their protection under intellectual property rights.

6.1.6 Dealing with violations of research integrity

It is of utmost importance that researchers acquire the knowledge, methodologies and ethical practices associated with their field. Failure to follow good research practices violates professional responsibilities. It damages the research processes, institutional and researchers' image, degrades relationships among researchers, undermines trust in and the credibility of research, wastes resources and may expose research subjects, users, society or the environment to unnecessary harm. Therefore, it is the mandate of institutions to have clear procedures for dealing with research misconduct and other unacceptable practices. The RIO at national or institutional level will ensure ethical conduct of

research. RIO should have an official/administrator that is responsible for responding to reports of suspected research misconduct and a documented procedure or policy in place for doing so.

Research misconduct is traditionally defined as fabrication, falsification, or plagiarism (the so-called FFP categorisation) in proposing, performing, or reviewing research, or in reporting research results.¹⁴⁷ Fabrication is making up results and recording them as if they were real while falsification is manipulating research materials, equipment or processes or changing, omitting or suppressing data or results without justification. Plagiarism is using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs. These three forms of violation are considered particularly serious offences since they distort the research record. There are further violations of good research practice that damage the integrity of the research process or of researchers. These include manipulating authorship, self-plagiarism, selective citation to enhance own findings or please editors, reviewers or colleagues, withholding research results or exaggerating the importance and practical applicability of findings, publishing in predatory journals, or ignoring putative violations of research. Although national and/or institutional guidelines differ on how violations of good research practice or allegations of misconduct are handled it always is in the interest of society and the research community that violations are handled in a consistent, fair and transparent manner, and with integrity. A serious breach of research rules that is carried out with intent or recklessness or negligence is particularly egregious and may be referred to as research misconduct. Institutions must develop a guide to use to investigate and manage potential breaches, determine any corrective actions to ensure the integrity of the research record and when a finding of research misconduct may be made.

The following principles and guidelines need to be incorporated into any investigation processes:

- It is crucial that an institutional process for dealing with these issues exists,
- Investigations are fair, transparent, comprehensive and conducted expediently, without compromising accuracy, objectivity or thoroughness,
- The parties involved in the procedure declare any conflict of interest that may arise during the investigation,
- Measures are taken to ensure that investigations are carried through to conclusion,
- Procedures are conducted confidentially in order to protect those involved in the investigation,

¹⁴⁷ Available at <https://allea.org/code-of-conduct/>

- Institutions protect the rights of whistle blowers during and after investigations and ensure that their career prospects are not endangered,
- General procedures for dealing with violations of good research practice are publicly available and accessible to ensure their transparency and uniformity,
- Investigations are carried out with due process and in fairness to all parties,
- Persons accused of research misconduct are given full details of the allegation(s) and allowed a fair process for responding to allegations and presenting evidence,
- Action is taken against persons for whom an allegation of misconduct is upheld, which is proportionate to the severity of the violation,
- Appropriate restorative action is taken when researchers are exonerated of an allegation of misconduct,
- Anyone accused of research misconduct is presumed innocent until proven otherwise,
- Ensure that the process for managing and investigating concerns or complaints about potential breaches is timely, effective and in accord with procedural fairness,
- Support the welfare of all parties involved in an investigation of a potential breach of the research conduct guidelines,
- Base findings of investigations on the balance of probabilities and ensure any actions are commensurate with the seriousness of the breach,
- Facilitate the prevention and detection of potential breaches of research conduct,
- Provide mechanisms to receive concerns or complaints about potential breaches of the research conduct. Investigate and resolve potential breaches,
- Facilitate that parties involved in breach of research conduct learn from bad practices to avoid making same mistakes again, and
- Monitor and decisively deal with nepotism (where researchers hire relatives, close friends, regardless of their merits and abilities), favouritism and corruption as they affect the integrity of research and pose a serious threat to the economic system, the country's legal system and sustainability of organisations and nations at large (Gjinovci, 2016; Bekesiene et al., 2021).

6.2 Researchers

Researchers must be guided by the fundamental principles of research integrity in their research and engagement with the practical, ethical and intellectual challenges inherent in research. This applies to researchers across all disciplines and for all research types. These principles include reliability, honesty, respect for colleagues and research participants or subjects, accountability and rigour as alluded to in section 3. This is because researchers must employ rigorous methodologies for

conducting quality research; they should be honest and transparent when communicating research to all stakeholders, have respect for themselves, colleagues and research subjects and be accountable of the research throughout its processes from conception of ideas to publication of findings at various platforms and in various forms. Following methodologies as reflected in the study design, the analysis of data and the use of resources is pertinent. Subsequently, widespread adoption of proper research ethics and integrity by researchers gives confidence to research funders with greater confidence in the integrity of research. The role of funders is elaborated below. In addition to the above research principles, researchers must adhere to research practices. These include but are not limited to, training, supervision and mentoring; research procedures; safeguarding, data practice and management, publication and dissemination; reviewing, evaluating and editing.¹⁴⁸ Furthermore, researchers are expected to be aware of and comply with the applicable laws, codes, regulations and guidelines that apply to the conduct of research or national laws (see section 5).

6.2.1 Responsibilities of researchers

Researchers are expected to uphold the principles of responsible research conduct in all aspects of their research. The following responsibilities are outlined.

a) Research ethics

As alluded to before that researchers' obligation is to adhere to all applicable research ethics principles when conducting research, the following is expanded to support the assertion. Researcher of all type of research in all disciplines are expected to:

- Ensure that appropriate approvals are obtained prior to the commencement of research, and that conditions of any approvals are adhered to during the course of research and after the research,
- Ensure that the ethics principles of research merit and integrity, justice, beneficence and respect are applied to human research,
- Engage with indigenous peoples and respect their cultural values, customs, knowledge, contribution and Intellectual property rights,
- Ensure that the 4Rs (Replacement, Reduction, Refinement and Responsibility) are considered at all stages of research involving animals and minimise the impacts on animals used in research and in so doing support the welfare and wellbeing of these animals,
- Comply with the laws and regulations for the conservation and protection of biodiversity,

¹⁴⁸ Available at <https://allea.org/code-of-conduct/>

- Disclose and manage actual, potential or perceived conflicts of interest,
- Cite and acknowledge other relevant work appropriately and accurately,
- Handle research subjects; human, animal, cultural, biological, environmental or physical, with respect and care, and in accordance with legal and ethical provisions,
- Have due regard for the health, safety and welfare of the community, collaborators and others connected with their research,
- Have research protocols that take account of, and are sensitive to, relevant differences in age, gender, culture, religion, ethnic origin and social class. This is key to promote equity and equality or redress inequality and enhance inclusivity,
- Recognise and manage potential harms and risks relating to their research.

b) Research integrity

Despite the fact that the principles that are considered to constitute research integrity vary in different statements and national policies and also across disciplines, researchers are expected to comply with their government and research institutional guiding regulations for good conduct of research. Researchers must support a culture of responsible research conduct at their institutions and in their field of practice. As such, researchers should:

- Provide guidance and mentorship on responsible research conduct to other researchers or research trainees under their supervision and, where appropriate, monitor their conduct,
- Undertake and promote education and training in responsible research conduct,
- Comply with the relevant laws, regulations, disciplinary standards, ethics guidelines and institutional policies related to responsible research conduct,
- Ensure that authors of research outputs are all those, and only those, who have made a significant intellectual or scholarly contribution to the research and its output, and that they agree to be listed as an author. Not forgetting to comply with good and recommended ethical standards to deceased authors who contributed to the research outputs,
- Acknowledge those who have contributed to the research,
- Participate in peer review in a way that is fair, rigorous and timely and maintains the confidentiality of the content,
- Report suspected breaches of the research conduct to the relevant institution and/or authority,
- Make datasets available for inspection and/or reproducibility of research,
- Consider the state-of-the-art in developing research ideas,

- Design, conduct, analyse and document research in a careful and well considered manner. It is pertinent to adopt methods appropriate to the aims of the research and ensure that conclusions are justified by the results,
- Make proper accountable and conscientious use of research funds,
- Publish results and interpretations of research in an open, honest, transparent and accurate manner, and respect confidentiality of data or findings when legitimately required to do so,
- Report their results in a way that is compatible with the standards of the discipline and, where applicable, can be verified and reproduced. Disseminating research findings responsibly, accurately and broadly is paramount. Where necessary, take action to correct the record in a timely manner,
- Comply with principles and regulations relevant to their discipline, and
- Retain clear, accurate, secure and complete records of all research including research data and primary materials as data storage or archiving and management is crucial. Where possible and appropriate, allow access and reference to these by interested parties bearing in mind ethical rules, funders and other collaborators' policies and regulations and/or contractual guidelines.

6.3 Research ethics committees (RECs)

6.3.1 The role of RECs

Several international guidelines stipulate that all research involving human participants, biological or genetic data, animals and radiological material or the environment should get reviewed by an independent REC before the research is conducted. The purpose of RECs is to ensure that research is conducted in compliance with the highest ethical standards. This is done by reviewing research protocols to ensure that the dignity, rights, safety, and well-being of all research participants are safeguarded, and that animals' rights, the environment and biodiversity are protected. RECs are responsible for acting in the full interest of potential research participants and concerned communities, taking into consideration the interests and needs of the researchers and institutions, and having due regard for the requirements of appropriate regulatory authorities and applicable laws. They also need to ensure that there is regular evaluation and monitoring of the ethics of ongoing studies that have been approved. Countries, institutions, and communities should strive to establish RECs and develop ethical review structures that ensure the broadest possible coverage of protection for potential research participants and ethical use of biological or genetic data, animals, the

environment or radiological material. No research should take place without having prior ethics approval, if required.^{149,150}

6.3.2 Establishing a system of research ethics review

The RECs and ethical review systems must contribute to the highest possible quality in the science and ethics of research. States should promote, as appropriate, the establishment of RECs at the national, institutional, and local levels that are independent, multi-disciplinary, multi-sectorial, and pluralistic in nature. These should be provided with administrative and financial support to function effectively.¹⁵¹

Procedures need to be established for relating various levels of review in order to ensure consistency and facilitate cooperation between researchers and RECs. Mechanisms for cooperation and communication need to be developed between national committees and institutional committees. These mechanisms should ensure clear and efficient communication. They should also promote ethical research practices within a country as well as the ongoing education of members of ethics committees. Procedures need to be established for the review of research protocols carried out at more than one site in a country or in more than one country.

RECs should also keep up with new advancements and shifting contexts that may necessitate flexibility and innovation. To this end, the global COVID-19 pandemic, for example, demands multicentre and transnational research cooperation. Considering the COVID-19 public health emergency, the regular deadlines for research ethics approval must be shortened without jeopardizing the review process' fundamental protections.¹⁵² Furthermore, research undertaken at this time must take other public health activities into account, and these studies should never jeopardize the public health response to the pandemic or the provision of proper clinical care. Mechanisms will also be needed to limit conflicts of interest, particularly political conflicts; timely and widespread disclosure of information, including findings and relationships with sponsors, especially drug firms.¹⁵³

¹⁴⁹ World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

¹⁵⁰ Council for International Organisations of Medical Sciences. 2021. "Clinical Research in Resource Limited Settings" Geneva. Available at <https://cioms.ch/publications/product/clinical-research-in-low-resource-settings/>

¹⁵¹ World Health Organisation. 2020. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

¹⁵² Research Ethics Support in COVID-19 Pandemic (RESCOP): Proposed Rapid Review Process For South African RECs. Available at <https://www.vut.ac.za/wp-content/uploads/2020/04/RESCOP-2020-PROPOSED-RAPID-REVIEW-PROCESS.pdf>

¹⁵³ Research Ethics Support in COVID-19 Pandemic (RESCOP): Proposed Rapid Review Process For South African RECs. Available at <https://www.vut.ac.za/wp-content/uploads/2020/04/RESCOP-2020-PROPOSED-RAPID-REVIEW-PROCESS.pdf>

6.3.2.1 Constituting a REC

RECs should be constituted to ensure the competent review and evaluation of all ethical aspects of the research projects they receive and to ensure that their tasks can be executed free from bias and influence that could affect their independence. RECs should be multidisciplinary and multi-sectoral in composition, including relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and the concerns of the community that they serve.

RECs should be established in accordance with the applicable laws and regulations of the country and in accordance with the values and principles of the communities they serve. RECs should establish publicly available standard operating procedures that state the authority under which the committee is established, the functions and duties of the REC, membership requirements, the terms of appointment, the conditions of appointment, the offices, the structure of the secretariat, internal procedures, and the quorum requirements. RECs should act in accordance with their written operating procedures. It may be helpful to summarize the activities of the REC in a regular (annual) report.

a) Membership for Human Research Ethics Committees (HRECs)

RECs that review research that involves human participants should have members capable of providing competent and thorough review of research protocols. HREC membership should consist of:

- i) Physicians, scientists and other professionals such as social workers, nurses, psychologists etc,
- ii) At least one lay person or community member who can represent the cultural and moral values of study participants,
- iii) A member with expertise in biostatistics or research methods,
- iv) A member with expertise in research ethics,
- v) At least one member who is legally qualified,
- vi) Committees must include both men and women and should have ethnic balance, and
- vii) When a proposed study involves vulnerable individuals or groups, as may be the case in research involving prisoners or illiterate persons, representatives of relevant advocacy groups should be invited to meetings where such protocols will be reviewed.

b) Membership for Animal Research Ethics Committees (ARECs)

Membership for Animal Research Ethics Committees may include the following:¹⁵⁴

¹⁵⁴ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

- i) Veterinarians,
- ii) Scientists with substantial and recent experience in the use of experimental animals,
- iii) Animal welfare organization representatives,
- iv) Representatives not involved in animal experimentation or laypersons, and
- v) A member with legal background.

c) Membership for Biosafety RECs (BRECs)

The Biosafety REC may comprise of a minimum of five academics or researchers with various expertise and experience to review and assess all the matters referred to it for consideration, assessment, or advice. This may include experts in recombinant DNA technology and the use of (human, animal and plant) pathogens as well as other professionals who, in general terms, are able to evaluate the safety of research and teaching facilities and activities, and identify any potential risk to human health, animals and the environment.

d) Considerations for appointment of REC members

Regular rotation of members is desirable for balancing the advantage of experience with that of fresh perspectives.¹⁵⁵

Members of research ethics committees must regularly update their knowledge about the ethical conduct of health-related research. If committees do not have the relevant expertise to review a protocol adequately, they must consult with external persons with the proper skills or certification or discipline-specific knowledge. Conflicts of interest should be avoided when making appointments, but where unavoidable, there should be transparency with regard to such interests. Quorum rules should be adjusted to reflect the size of the committee but should always include at least one member from each category of members.

e) Terms of appointment for REC members

Terms of appointment for each of the RECs described above should be established in standard operating procedures (SOPs) that include the following:¹⁵⁶

¹⁵⁵ Council for International Organisations of Medical Sciences. 2016. "International Ethical Guidelines for Health-related Research Involving Humans" Geneva. Available at <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

¹⁵⁶ World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>.

- i) The duration of an appointment,
- ii) The policy for the renewal of an appointment,
- iii) The disqualification procedure,
- iv) The resignation procedure, and
- v) The replacement procedure.

f) Conditions of appointment of REC members

A statement of the conditions of appointment should be drawn up that includes the following:¹⁵⁷

- i) A member should be willing to publicize his/her full name, profession, and affiliation,
- ii) All reimbursement for work and expenses, if any, within or related to a REC should be recorded and made available to the public upon request, and
- iii) A member should sign a conflict of interest and confidentiality agreement regarding meeting deliberations, applications, information on research participants, and related matters; in addition, all REC administrative staff should sign similar conflict of interest and confidentiality agreements.

g) Expectations of institutions regarding RECs

- i) Countries and institutions should ensure that adequate administrative support and resources are provided so that the work of the RECs can be done in compliance with minimum standards,
- ii) Procedures and criteria for recruitment and appointment of REC members should be in place and transparent,
- iii) All members of RECs should be given a formal appointment letter that sets out, at a minimum, the term of office; where to find the necessary information for new members; and the assurance that members are indemnified from personal liability against claims that may arise in the course of the ordinary business of the respective REC. Terms and conditions such as confidentiality and conflict of interest declarations etc, should also be provided to members,
- iv) Opportunities for training and refresher courses in research ethics (human, animal and biosafety) should be made available or accessible for committee members and researchers. Committee members should receive research ethics training and orientation on appointment and should refresh at least once every three years. For the HREC, members who review clinical trial proposals should have Good Clinical Practice training, evidenced by a certificate issued not

¹⁵⁷ World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

more than two years previously or proof of registration with professional bodies for accreditation, and

- v) Institutions should indemnify committee members from personal liability and should ensure that adequate public liability insurance exists. The institution should take legal responsibility for the decisions and advice of the RECs, provided that members act in good faith.¹⁵⁸

h) Independent consultants

- i) RECs may call upon, or establish a standing list of, independent consultants who may provide special expertise to the REC on proposed research protocols. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, or they may be representatives of communities, patients, or special interest groups, and
- ii) Terms of reference for independent consultants should be established.

i) Training for REC members

REC members should be provided with initial and continued education and training on the ethics and science of research. The conditions of appointment should state the provisions available for REC members to receive introductory training in the work of a REC and ongoing opportunities for enhancing their capacity for ethical review. These conditions should also include the requirements or expectations regarding the initial and continuing education of REC members. This education may be linked to co-operative arrangements with other RECs in the area, the country, and the region and other opportunities for the initial and continued training of REC members.¹⁵⁹

6.3.2.2 Review of ethics applications

All properly submitted applications should be reviewed on time and according to an established review procedure.

a) Meeting requirements

RECs should meet regularly on scheduled dates that are announced in advance. The meeting requirements should include the following:¹⁶⁰

¹⁵⁸ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

¹⁵⁹ World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

¹⁶⁰ World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

- i) Meetings should be planned in accordance with the needs of the workload,
- ii) REC members should be given enough time in advance of the meeting to review the relevant documents,
- iii) Meetings should be minuted; there should be an approval procedure for the minutes,
- iv) The applicant, sponsor, and/or investigator may be invited to present the proposal or elaborate on specific issues, and
- v) Independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidentiality agreements.

b) Elements of the review

The primary task of a REC lies in the review of research proposals and their supporting documents, with special attention given to the suitability and feasibility of the protocol. RECs need to take into account prior scientific reviews, if any, and the requirements of applicable laws and regulations. The following should be considered in reviewing proposals, where necessary:

1. Scientific Design and Conduct of the Study

- i) The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest sample size,
- ii) The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants, concerned communities or animals,
- iii) The justification for the use of control arms in intervention studies,
- iv) Criteria for prematurely withdrawing of research participants or animals,
- v) Criteria for suspending or terminating the research as a whole,
- vi) The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring board (DSMB),
- vii) The adequacy of the site, including the supporting staff, available facilities, and emergency procedures, and
- viii) The manner in which the results of the research will be reported and published.¹⁶¹

¹⁶¹ World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

2. Sampling procedures

- i) The characteristics of the population from which the research participants, animals or environmental samples will be drawn,
- ii) The means by which initial contact and recruitment are to be conducted,
- iii) The means by which full information on the study procedures is to be conveyed to potential research participants or their representatives,
- iv) Inclusion criteria for research participants, biological or genetic material or animals, and
- v) Exclusion criteria for research participants, or animals.

3. Protection of Research Participant Confidentiality

- i) The measures taken to ensure the confidentiality and security of personal information concerning research participants, and
- ii) Description of the persons who will have access to personal data of the research participants, including medical records and biological samples.¹⁶²

4. Informed Consent Process

- i) A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent,
- ii) The adequacy, completeness, and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representative(s),
- iii) Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals,
- iv) Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety, and well-being), and
- v) The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.¹⁶³

¹⁶² World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

¹⁶³ World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

5. Care and Protection of Research Participants, Animals and the Environment

- i) The suitability of the investigator(s)'s qualifications and experience for the proposed study,
- ii) Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action,
- iii) The medical care to be provided to research participants or animals during and after the course of the research,
- iv) The adequacy of medical supervision and psycho-social support for the research participants,
- v) Steps to be taken if research participants voluntarily withdraw during the course of the research,
- vi) The criteria for extended access to, the emergency use of, and/or the compassionate use of study products,
- vii) The arrangements, if appropriate, for informing the research participant's general practitioner (family doctor), including procedures for seeking the participant's consent to do so,
- viii) A description of any plans to make the study product available to the research participants following the research,
- ix) A description of any financial costs to research participants,
- x) The rewards and compensations for research participants (including money, services, and/or gifts),
- xi) The provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research, and
- xii) Any insurance and indemnity arrangements.¹⁶⁴

6.3.2.3 Community considerations

- i) The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn,
- ii) The steps taken to consult with the concerned communities during the course of designing the research,
- iii) The influence of the community on the consent of individuals,
- iv) Proposed community consultation before and during the course of the research,

¹⁶⁴ World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

- v) The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs,
- vi) A description of the availability and affordability of any successful study product to the concerned communities following the research, and
- vii) The manner in which the results of the research will be made available to the research participants and the concerned communities.¹⁶⁵

6.3.2.4 Review categories

There are different levels of ethics review, categorised according to the level of risk inherent in a particular study. These include:

a) Exempt review or waivers

Some studies that present below minimum risk may be exempted from review. For example, when publicly available data are analysed or the data for the study are generated by observation of public behaviour, and data that could identify individual persons or groups are anonymized or coded, or individuals are being interviewed in their official capacity on issues that are in the public domain, the study may be exempted.¹⁶⁶

b) Expedited Review

RECs should establish procedures for the expedited review of research proposals. These procedures should specify the following:

- The nature of the applications, amendments, and other considerations that will be eligible for expedited review. For example, expedited review may apply, in principle, only to research that poses minimal risk of harm,
- The quorum requirement(s) for expedited review, and
- The status of decisions (e.g. subject to confirmation by full REC or not).

¹⁶⁵ World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

¹⁶⁶ Council for International Organisations of Medical Sciences. 2016. "International Ethical Guidelines for Health-related Research Involving Humans" Geneva. Available at <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

c) Full Committee Review

High risk studies (more than minimal risk) should be discussed at a full Committee meeting. Two main reviewers may be assigned to each protocol (primary and secondary reviewer) to review and present their findings at a full Committee meeting and have the Committee deliberate on the protocol.

6.3.2.5 Decision-making

In making decisions on applications for the ethical review of research, a REC should take the following into consideration:¹⁶⁷

- i) A member should withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes,
- ii) A decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g. the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of REC staff,
- iii) Decisions should only be made at meetings where a quorum (as stipulated in the REC's written standard operating procedures) is present,
- iv) The documents required for a full review of the application should be complete and the relevant elements mentioned above should be considered before a decision is made,
- v) Only members who participate in the review should participate in the decision,
- vi) There should be a predefined method for arriving at a decision (e.g. by consensus, by vote); it is recommended that decisions be arrived at through consensus, where possible,
- vii) When a consensus appears unlikely, it is recommended that the REC vote or the chair has a casting vote,
- viii) After the deliberative review process, the REC should approve, require amendment to, or reject a research application,
- ix) In considering a research protocol, the REC may seek assistance from experts, but such experts may have no conflicts of interest in relation to the application,
- x) Decisions of the REC should be recorded in writing,
- xi) A decision to approve should include the conditions, e.g. the duration of the approval, the reporting requirements, etc,
- xii) A decision to require amendment or to reject, should record reasons for the decision,

¹⁶⁷ World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

- xiii) Outright rejection should be avoided if a researcher can be advised to improve the proposal.
- xiv) In some cases, a researcher may be invited to the REC meeting to explain his/her proposal if it is not clear to REC members,
- xv) The educative role of RECs should be fostered, which means that, where possible, researchers should be encouraged to engage with the concerns and seek to improve their protocols,
- xvi) Feedback should be instructive to assist the researchers to improve the application if appropriate,
- xvii) Feedback should be sufficiently detailed so that the concerns of the REC are understandable to the researchers,
- xviii) RECs should require researchers to report immediately anything that might warrant reconsideration of ethical approval of the protocol, including but not limited to: serious or unexpected adverse effects on participants, proposed changes in the protocol, unforeseen events that might affect continued ethical acceptability of the project, and
- xix) RECs should require researchers to report immediately if a project is terminated or suspended before the anticipated date of completion.

6.3.2.6 Conflicts of interest and independence of review

- i) Research ethics committees must provide independent ethical opinions. Pressure can be brought to bear from many different directions, not just financial. Research ethics committees must therefore have mechanisms to ensure the independence of their operations. In particular, they must avoid any undue influence and minimize and manage conflicts of interests. Research ethics committees must require that their members disclose to the committee any interests they may have that could constitute a conflict of interest or otherwise bias their evaluation of a research proposal. Research ethics committees must evaluate each study in light of any disclosed interests and ensure that appropriate steps are taken to mitigate possible conflicts of interest. Research ethics committees may receive a fee for reviewing studies. However, this need not constitute a conflict of interest,¹⁶⁸
- ii) REC members should disclose information that may lead to perceptions of conflict of interest,
- iii) REC members should not review or make decisions about research proposals they are involved in personally or financially. When such a proposal is to be discussed, the member concerned should declare the potential conflict and offer to recuse herself from the meeting for that time.

¹⁶⁸ Council for International Organisations of Medical Sciences. 2016. "International Ethical Guidelines for Health-related Research Involving Humans" Geneva. Available at <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>.

Should the member be permitted to remain for the discussion at the Chairperson's discretion, the member may not participate in the final decision-making on the application in question.¹⁶⁹

6.3.2.7 Monitoring

- i) Research ethics committees must be authorized to monitor ongoing studies. The researcher must provide relevant information to the committee to monitor research records, especially information about any serious adverse events,
- ii) The frequency and type of monitoring should reflect the degree and extent of risk of harm to participants or animals,
- iii) RECs may recommend and adopt any additional appropriate mechanism for monitoring, including random inspection of research sites, welfare monitoring sheets, data and signed consent forms, and records of interviews. Information and consent materials should indicate that such monitoring may take place,
- iv) RECs should request regular, at least annual reports from principal investigators on matters including but not limited to progress to date, or outcome in the case of completed research, current enrolment status (numbers, active or closed), whether participant follow-up is still active or completed information concerning maintenance and security of records evidence of compliance with the approved protocol evidence of compliance with any conditions of approval negative reports from monitors or Good Clinical Practice (GCP) inspectors list all adverse events in the past 12 months list all amendments made in the past 12 months,
- v) RECs should inform principal investigators in writing of concerns arising from such monitoring activities, and
- vi) Following the analysis of the study data, researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.¹⁷⁰

6.3.2.8 Protocol amendments, deviations, violations and sanctions

- i) During the study, deviations from the original study might occur, such as changes in the sample size or analysis of the data as described in the protocol. Deviations must be reported to research ethics committees. In the case of permanent deviations, researchers may write an amendment. The research ethics committee must decide whether a deviation is legitimate or illegitimate. Protocol violations are deviations from the original protocol that significantly affect the rights or interests of research participants and impact substantially the scientific validity of the data.

¹⁶⁹ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

¹⁷⁰ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

In the case of protocol violations, research ethics committees should ensure that study participants will be informed, and provision will be made to protect their safety and welfare,¹⁷¹ and

- ii) Research ethics committees generally do not have the authority to impose sanctions on researchers for protocol violations or violations of ethical standards in the conduct of research. However, committees may halt the continuation of a previously approved protocol if it finds protocol violations or other misconduct on the part of researchers. Committees must report to the sponsor and institutional or governmental authorities any serious or continuing non-compliance with ethical standards in the conduct of previously approved research projects.¹⁷²

6.3.2.9 Suspension or discontinuation of projects

- i) Where circumstances indicate that a project is non-compliant with the approved protocol and the interests of participants are at risk of harm, the REC may withdraw approval, after due process has been followed,
- ii) A clear process should be followed that permits swift but proper investigation and decision-making to ensure protection of participants. The investigation should include interaction with the researchers and other interested parties to ensure a fair and transparent process,
- iii) If the decision is to withdraw approval, the REC should inform the principal investigator and other interested parties, including the institutional authorities, and recommend suspension (temporary stoppage) or termination (permanent stoppage) of the project. It should also recommend remedial action where appropriate, and
- iv) In the case of suspension, the principal investigator should comply with the recommendations and any special conditions imposed by the REC.¹⁷³

6.3.2.10 Complaints

- i) Each REC should have a complaints process that is accessible to researchers and other interested persons. In principle, but subject to institutional requirements, complaints about REC-related business should be directed to the REC in the first instance. If the matter remains unresolved, it may be escalated to other specified institutional officials and then to the national REC where applicable,

¹⁷¹ Council for International Organisations of Medical Sciences. 2016. "International Ethical Guidelines for Health-related Research Involving Humans" Geneva. Available at <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

¹⁷² World Health Organisation. 2000. "Operational Guidelines for Ethics Committees That Review Biomedical Research" Geneva. Available at <https://www.who.int/tdr/publications/documents/ethics.pdf>

¹⁷³ Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

- ii) A standard operating procedure should detail the procedures to be followed,
- iii) The national REC should be empowered to adjudicate complaints about RECs and to hear a complaint from any researcher who believes that they have been discriminated against unfairly by any REC,
- iv) The national REC should adhere to the following principles when investigating a complaint: fairness, confidentiality, integrity and prevention of detriment, and
- v) All information and consent documentation should include contact details for making complaints about being a research participant. Similarly, a research assistant, researcher or an interested community member should be able to lodge a complaint or grievance related to the research process.

7. FUNDERS / SPONSORS

Member States need to factor in their policy mechanisms that negotiations with funders or sponsors be on the terms of fair and equitable partnerships. This could include assessing whether there are any power imbalances and determining what is the driver behind this. For example,

- What conditions need to be clarified before the research is approved and signed, including
- the collection/extraction mechanisms /further use/consent, etc.?
- Who are all the role players in the research study (funder, sponsor, researchers, and research institutions)?
- What is the risk-benefit ratio concerning fair/equitable partnerships throughout the process, including negotiations around mutually 'beneficial' terms (mutually agreed terms must benefit indigenous communities)?
- What safeguards could be put in place for researchers from developing countries to protect them from potentially exploitative collaborations?

Funders are responsible for implementing and maintaining quality assurance and quality control systems with written standard operating procedures (SOPs) to ensure that research in general and trials in particular are conducted, and data generated, documented (recorded) and reported in compliance with the protocol.

The funder is responsible for the following:

- Securing the research agreement from all stakeholders and parties involved,

- Ensuring direct access to research sites,
- Permission to examine, analyse, verify and reproduce records and reports that are important to the research,
- ANY party, domestic and foreign regulatory authorities, sponsor's monitors and auditors, with direct access to research sites must take all reasonable precautions within the constraints of the applicable regulatory requirements to maintain the confidentiality of participants' identities and sponsor's propriety information, and
- Agreements made by the sponsor with the investigator/institution and the community must be in writing, as part of the protocol or in a separate agreement.

8. RECOMMENDATIONS

It is recommended that SADC countries and research institutions should have clear research ethics and integrity policies and frameworks that guide researchers to conduct responsible research and in a reputable manner. Capacity building mentorship and coaching of all researchers, research ethics officers and ethics administrators in research ethics and integrity should be widely and regularly offered in the region. Such training should be incorporated into accredited continued capacity development. Regional and national monitoring and evaluation of research ethics and integrity is recommended and appropriate handling of violations and allegations of misconduct should be done. This should be handled in all fairness and integrity. The region should have guidelines on handling violations of responsible research practice. Member States should also establish key mechanisms for harmonisation at the national and regional levels, such as a SADC Research Ethics and Integrity Community of Practice (CoP), a Portfolio Committee/Working Committee, or other appropriate forums with representation from all 16 Member States.

9. APPENDIX 1

Table 1: Limitations related to ethics and implementation of the Nagoya Protocol faced by countries in the Southern African development (SADC) region

COUNTRY	LIMITATION	SOURCE
Angola	<p>Responsibilities for managing genetic resources, including Access Benefit Sharing (ABS), seems unclear because the country has different institutions granting access to the genetic resources. There is, therefore, a need for these institutions to clearly define responsibilities.</p> <p>Uses of native plants have not been systematically catalogued and analysed. The sharing of benefits with indigenous communities is not yet effective.</p> <p>Lack of awareness of the NP and its requirements, in particular the legal context of mutually agreed terms (MAT) in order to ensure compliance at airports and national borders and framework to promote the principles of the NP.</p> <p>Capacity building with respect to NP compliance is a key issue in Angola, to engage national institutions and define responsibilities, and also the designation of checkpoints; lack of information as to what the developed capacity-building activities, institutional support, research collaboration and infrastructure entail. Likewise, it is not clear the extent to which IKS has been incorporated into ABS systems.</p> <p>Lack of ABS legislation and lack of trained staff and application of biotechnological research activities.</p>	Göhre et al. (2016)
Comoros	<p>There is little available information on ethics and governance issues in Comoros.</p> <p>Comoros has been observed as the weakest nation in sub-Saharan Africa in terms of ethics procedures for health research.</p> <p>Lack of capacity is a significant limitation in the extent to which Comoros can enact the principles of the NP. The domestic legislative basis on which ABS measures are based is not always well developed.</p> <p>No provision on access to traditional knowledge associated with genetic resources has yet been established in Comoros. Therefore, capacity building, establishment of an information system for the collection and sharing of data, and awareness campaigns are needed.</p>	Mbondji et al. (2014)
Botswana	<p>Several studies have examined research ethics in Botswana. The University of Botswana is a key player here in research ethics training. These studies show that training increases ethics awareness and identification of research ethics issues.</p> <p>Despite concerted efforts in ethics training the number of individuals with adequate training in research ethics to meet growing demand remains small.</p> <p>Although there is as yet no specific ABS, prior informed consent (PIC) measures are in place at the Department of Agricultural Research and the Research Unit of the Ministry of Environment, Natural Resources and Tourism. These include permits obtained for research, filming, photography and harvesting of natural resources.</p>	Mazone et al. (2007), Barchi et al. (2013), Ralefala et al. (2018), Deutsch-Feldman et al. (2020)
Democratic Republic of the Congo	<p>Key limitations identified include a lack of capacity and training There is also uncertainty in the relevant institutional review boards (IRBs) in the country, and there are different procedures in place for different institutions--- this needs to be harmonised at national level-global-regional-national-institutional like what happens with the sustainable development goals (SDGs).</p>	Ravinetto et al. (2010).

COUNTRY	LIMITATION	SOURCE
Eswatini	Lack of institutional frameworks, and lack of understanding of the issues amongst different stakeholders	http://extwprlegs1.fao.org/docs/pdf/swa170338.pdf
Lesotho	Not well coordinated genetic and biological data research, collaboration, material transfer and access benefit and sharing. Missing overarching regulatory frameworks	https://www.cbd.int/doc/nr/nr-06/ls-nr-06-en.pdf
Madagascar	Ordinance No. 89-019 of July 31 1989, for the establishment of regulations for Intellectual Property (IP), does not say anything about the legal status of indigenous knowledge in general or genetic resources in particular. Limitation on protection of data obtained through IKS although Limited information and awareness raising amongst stakeholders There is little available information on research ethics frameworks and practices	
Malawi	Consistency of process for issuance of permit may be violated as different bodies issue permits. General limitations in compliance to the NP and future activities include public awareness and training in particular in ABS; inadequate understanding of the roles of different institutions; lack of standalone ABS legislation; and frameworks in place to monitor compliance of MAT. (Institutions)	https://absch.cbd.int/api/v2013/documents/OD99AF1D-68C7-153A-3E31-2D7CB1534221/attachments/Malawi-access96.pdf Kumwenda-Mtande (2018)
Mauritius	Gaps in legislation, inadequate human and financial resources, limited research, lack of qualified personnel	Mootoosamy and Mahomoodally, 2014
Mozambique	No specific statutory guidelines or frameworks overarching issues limiting NP compliance include lack of institutional capacity, administrative capacity, training, financial resources, stakeholder awareness and identification of best practice.	Ashwe (2014)
Namibia	Lack of coordinated research and development into genetic resources with potential commercial applications; and ensuring sustainable harvesting of resources There are also institutional resource capacity issues. There is a lack of coordination between different government actors. There is also lack of resources to develop and implement suitable administrative functions for monitoring compliance. Research ethics practices in Namibia are not well documented Key issues include increasing awareness, training and technical capacity in particular amongst indigenous communities; establishing an effective genetic resources unit; strengthening the role of traditional authorities and customary law as relates to ABS in accordance to article 100 of the Namibian Constitution; designing and implementation of a mechanism for the documentation and protection of IKS	Chinsembu and Chinsembu (2020)
Seychelles	Limited information on policies developed towards NP compliance. Development of IKS policies is underway but they focus more on community culture rather than genetic and biological diversity and knowledge. Institutions should ensure that developed policies cover all research niche areas or disciplines	

COUNTRY	LIMITATION	SOURCE
South Africa	<p>One important point to note is that the legislation refers to 'biological resources' and not 'genetic resources'</p> <p>Existing challenges include industry resistance in concluding ABS agreements with traditional knowledge holders, and human resource capacity issues. The government, research institutions and industry should collaboratively work together to address this matter.</p>	Lewis (2010), Nöthling Slabbert (2011), Moodley (2013)
Tanzania	<p>Widespread lack of funding, staff and skills in key national bodies causes a substantial gap between policy ambitions and reality.</p> <p>Very little information on IKS in Tanzania is available.</p>	https://assets.publishing.service.gov.uk/media/5ef4ad91e90e075c50609d56
Zambia	<p>Albeit, research ethics practices in Zambia are fairly well developed, ABS procedures are not clear</p>	Nkhata et al. (2012)
Zimbabwe	<p>Limited engagement with the NP.... There is mention of genetic resources but no description of what this means or how it can be evaluated. Meaning policies and legislative documents must be very clear and all terms and concepts must be well defined</p> <p>There were discrepancies with international guidelines for review, monitoring and membership of Research Ethics Committees (RECs) in Zimbabwe</p> <p>Pertaining some Zimbabwean REC there are significant issues to do with PIC</p>	Mielke and Ndebele (2004), Madanhire (2018)

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SOUTHERN AFRICAN DEVELOPMENT COMMUNITY RESEARCH ETHICS TOOLKIT

Prepared by the Northern Regions Community of Practice for Ethics and Integrity in Southern Africa in collaboration with the Southern African Research Innovation and Management Association and Management Association and Southern Africa Network for Biosciences (SANBio)

NOVEMBER 24, 2021

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BACKGROUND

The Southern African Research & Innovation Management Association (SARIMA), together with the Southern Africa Network for Biosciences (SANBio) has subcontracted the services of a consultant to develop a regional Guidelines and Toolkit for Research Ethics in the Southern African Development Community (SADC) region. The aim is to support researchers at research institutions, national research centres, universities and private sector companies to adhere to principles of ethical research methodologies and policies particularly those involving indigenous knowledge or traditional knowledge. This is to support the implementation of the SADC Protocol on Science, Technology and Innovation, with particular reference to indigenous knowledge, its technologies and commercialisation.

ABBREVIATIONS

ABS	Access and Benefit-Sharing
DTA	Data Transfer Agreement
MTA	Material Transfer Agreement
NDA	Non-disclosure Agreement
PIC	Prior Informed Consent
SADC	Southern African Development Community

SECTION 1: FIRST STEPS

1.1 What is Research Ethics, Indigenous Knowledge, Access and Benefit-Sharing, and Why is it Important for the SADC Region?

The Singapore Statement on Research Integrity (2010) states the following in its preamble: “The value and benefits of research are vitally dependent on the integrity of research. While there can be and are national and disciplinary differences in the way research is organised and conducted, there are also principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken.” These principles and professional responsibilities form the framework for research ethics, which can be defined as the moral principles that govern how researchers conduct themselves in their research activities.

These guidelines concern research ethics to support the SADC Protocol on Science, Technology and Innovation (STI) signed by the Heads of States in 2008 and entered enforcement in 2017. One of the primary objectives of the SADC Protocol on STI is the promotion of Indigenous Knowledge Systems

(IKSs) and its technologies, especially in rural communities; protection of Intellectual Property Rights (IPRs); and promotion of gender equity and equality for STI. The guidelines equip the individual researchers, research institutions, technology transfer officers and national governments within the SADC region with the knowledge to adhere to principles of ethical research methodologies and policies, particularly those involving indigenous knowledge or traditional knowledge. The guidelines can be used as a standardised approach to applying moral ethical and professional codes of research integrity and conduct, and good ethical practices when undertaking research to the benefit of the national STI policies and SADC regional integration. The guidelines provide a practical approach on engaging with SADC indigenous communities; the design, instrumentation or data collection methods to be used; data reporting, data management, data storage and sharing; and reporting of the data to the indigenous knowledge communities who have contributed to the research.

The Convention on Biological Diversity (CBD), under the United Nations, has three objectives:¹

- i) The conservation of biological diversity,
- ii) The sustainable use of its components, and
- iii) The fair and equitable sharing of benefits arising out of the utilisation of genetic resources and its associated traditional knowledge.

The third objective listed above has also been developed into a separate field of academic and legal practice, of access to genetic resources and benefit-sharing (ABS). Parties to the CBD, which are national governments globally, have formalised approaches towards ABS that are specified through certain Articles of the CBD. Subsequently, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation was developed in 2010 to focus on ABS.

While each institution within the SADC region may have one or several Research Ethics Committees established to provide overall guidance on research ethics and approval of research ethics applications, there is often no clear guidance and tools to help them comply with national IKS and ABS policies or frameworks, as well as internationally accepted research ethics standards in their IKS and access and benefit-sharing activities.

¹ Convention on Biological Diversity (1992, 3rd ed 2005), available at <https://www.cbd.int/doc/handbook/cbd-hb-all-en.pdf>

1.2 Purpose of this Toolkit

This is a document that provides voluntary guidance and tools on RE and ABS practices to help researchers, research institutions, governments and private companies consider important aspects associated with research ethics and ABS (Crouch et al., 2008). The aim of this activity is to empower these targeted stakeholders to engage effectively in an ethical manner with the communities on indigenous knowledge for research, commercialisation and policy purposes.

The toolkit provides both users and providers of genetic resources and traditional knowledge with a structured and standardised process for fair and equitable means of participating in, and a methodology for making decisions, about ABS. This includes methods for conducting negotiations and the implementation of ABS agreements for access to and agreed use of genetic resources and its associated traditional knowledge with a wide range of stakeholders. The toolkit also informs those that are involved in research activities about the importance of research integrity and research ethics as listed in the Singapore Statement (2011) and the Hong Kong Principles (2019). An important aspect in RE and ABS is trust between providers (communities), users (researchers, research institutions and companies) and regulators (governments). The toolkit's purpose is to aid both users and providers of genetic resources and associated traditional knowledge, in a politically-neutral way, to help them establish necessary relationships based on confidence and trust. The toolkit is intended to apply to all stages of bioprospecting, of access to biological and genetic materials (collection and discovery), academic research, and research and development for commercial purposes.

1.3 Who can use this Toolkit

The toolkit is intended for use by users of genetic resources, particularly research institutions, researchers, regulators, indigenous communities, and a range of end users (e.g. industry).

1.3.1 Research institutions and researchers

This Toolkit aims to assist research institutions and individuals, NGOs, international partners, government agencies and departments across SADC, and private commercial and industrial companies who aim to use traditional knowledge (associated with a genetic resource) and collect genetic resources for research and development purposes. It should therefore enable them to:

- i) Voluntarily adopt a RE and ABS standard of practices which facilitates access to genetic resources by ensuring compliance with the CBD, and
- ii) Adopt good practices (e.g. collection permits) in accessing genetic resources and its associated traditional knowledge and providing fair and equitable benefits from their use.

1.3.2 Indigenous communities

The research ethics and ABS Toolkit is also targeted to genetic resource and traditional knowledge provider communities (i.e. indigenous and local communities) to:

- i) Help them make decisions about granting access of different types by increasing their understanding of the requirements under the Nagoya Protocol and responsible practices, and
- ii) Determine certain expectations and requirements in negotiating agreements for access to and use of genetic resources and its associated traditional knowledge to certain other stakeholder communities, in particular commercial companies and end users.

1.3.3 National governments on STI and ABS

Apart from assisting governments in their role as regulators of the use of genetic resources within their countries, the research ethics and ABS Toolkit can also help inform governmental authorities (agencies, departments and partners) of the requirements and practices necessary when conducting ABS activities, and to use the Toolkit and associated Guidelines document as a capacity building tool to increase awareness of ABS activities and procedures.

SECTION 2: ACCEPTED STANDARDS FOR RESEARCH ETHICS

2.1 Researcher/Research Institutions

2.1.1 Prior informed consent (PIC)

As part of responsible research conducted by researchers with human participants, informed consent must be obtained before research may commence. The researcher needs to have gained knowledge in all cultural practices and belief systems of the population group that they will involve in their study prior to the informed consent process. The informed consent process consists of three important elements: capacity, information and voluntariness. These three key elements guide the informed consent process (World Medical Association, 2013).

i) Capacity

A human participant needs to:

- a) Have sufficient intellectual and emotional capacity to make an informed decision,
- b) Understand the reason why they have been invited to participate in the study, and
- c) Understand the aim and objectives of the study and what is expected of them.

ii) Information

A human participant needs to:

- a) Identify the researcher, funders and their affiliations, as well as the name of the research ethics committee that has approved the research study,
- b) Be informed about the time and duration of the study,
- c) Be informed about the kind of compensation or reimbursement, if any, available to them while taking part in the study,
- d) Be informed of the potential risks and discomforts of being part of the study, both direct and indirect or implied (e.g. loss of wages, reputation, stigmatisation, etc.),
- e) Be informed of the anticipated benefits of being part of in the study, both direct, indirect or implied benefits (e.g. future peer group benefit, group interaction raising levels of belonging or self-worth, etc.). In clinical studies, the researcher needs to ensure that there is no therapeutic misconception when taking part in the study, and
- f) Be informed of the safeguards that will be taken to protect their confidentiality and privacy while being part of the study and of their records when the study has been finalised.

iii) Voluntariness

A human participant needs to:

- a) Be free and without coercion to decide if they want to take part in a study,
- b) Be afforded enough time to discuss their involvement in the study with their spouses, partners and/or family members, and
- c) Know that they may withdraw at any stage from the study without fear of reprisal.

2.1.2 Ethics review of research projects

Research projects involving the use of indigenous knowledge, humans, animals and the environment (e.g. plants) are subject to prior ethics review and approval by a Research Ethics Committee (REC) at the institutional level. In addition, for projects impacted by the Nagoya Protocol on Access and Benefit-Sharing, this toolkit will provide a checklist of aspects to be considered by a REC. This checklist is based on internationally accepted standards for research ethics and integrity.

In the context of human research, RECs should be mindful of and consider the four basic ethics principles of:²

² Belmont Report (1979), available at <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.

- i) Respect for persons (autonomy),
- ii) Non-maleficence,
- iii) Beneficence, and
- iv) Justice, which includes social and environmental justice.

In some SADC countries, for example South Africa, RECs apply the following core ethics principles as required by the Department of Health Ethics Principles in Health Research (2015), namely respect, scientific merit and integrity, distributive justice, and beneficence.

These general principles outlined above also apply to all forms of research that involve living persons, use of animals and other genetic and biological data and samples, thereby placing the safety, welfare and other interests of these materials as paramount when conducting research activities of different types within SADC. These general research principles also apply where research involves any type of human biological materials, any data collected from living or deceased persons, in particular where these data are identifiable to the individual, and can include human embryos, foetuses, foetal tissue, reproductive materials, and stem cells.

These guidelines hold a definition for 'human subjects research' as follows: "a human subject is a living individual about whom a researcher obtains (i) data through interventions or interactions; or (ii) identifiable private information".

2.1.2.1 Research Ethics Committees (RECs)

The main mandate of RECs is to protect vulnerable participants (i.e. local communities who are the holders of traditional knowledge associated with the indigenous genetic resources). In this regard, RECs act as gatekeepers to ensure that these communities are not exploited and unduly coerced during the research process. Aligned with international accepted standard of access and benefit-sharing (ABS), it is recommended that mutually agreed terms (MATs) between users and providers must be concluded prior to the start of the research project.

In this context traditional knowledge means: "Traditional knowledge refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems,

and knowledge embodying traditional lifestyles of indigenous and local communities or contained in codified knowledge systems passed between generations”.³

This Best Practice Standard acknowledges that the protection of traditional knowledge should occur in accordance with the relevant national legal framework (legislation, policies, guidelines, standards, codes, etc.) and practices. It is therefore recommended that RECs are familiar with their national legal framework relating to traditional knowledge.

The review of ethics applications and the methodology employed for ethics review by both RECs and by individuals in preparing their applications must be independent, unbiased, objective and informed. Therefore, certain standardised procedures need to be in place to facilitate this process and to provide uniformity and transparency. REC members must conduct themselves without fear or favour during the review process, and RECs must therefore balance the need to transparency with protecting its members and research ethics applicants. While the main responsibility of RECs is to protect potential and enrolled research participants, potential risks and benefits for the communities must also be considered. RECs must balance the ethics of any proposed research project, and any potential outcomes, over which of course the RECs have no control. The ultimate goal of any REC and its due process is to promote high standards of ethics in research with respect to the research community over which it has supervision. The ethical acceptability of a study includes, among other things, its social value and scientific validity.⁴

During the review process, RECs could consider the following principles to satisfy themselves that the proposed research is ethical (Emanuel et al., 2000):

- i) Social and scientific value,
- ii) Scientific validity,
- iii) Fair participant selections,
- iv) Favourable risk-benefit ratio,
- v) Independent review,
- vi) Informed consent,
- vii) Respect for participants (potential and enrolled), and
- viii) Collaborative partnership.

³ Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit-sharing Activities (2007), available at https://www.iisd.org/system/files/publications/abs_mt.pdf

⁴ CIOMS International Ethical Guidelines for Health-related Research Involving Humans (2016), available at <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

Institutions with oversight of human research, animal research and research using biohazardous material are encouraged to collaborate to assist researchers to protect the rights of participants, understand the risks associated with the research, and ensure compliance with animal welfare and health regulations.

2.1.2.2 Research integrity

The principles for research ethics, as enshrined in the Singapore Statement for Research Integrity (2010), apply throughout the research ecosystem from drafting a research proposal to closing out of a research project, and everything in between. These principles are:

- i) Honesty in all aspects of research,
- ii) Accountability in the conduct of the research,
- iii) Professional courtesy and fairness in working with others, and
- iv) Good stewardship of research on behalf of others.

This ecosystem includes all phases of the research life cycle: from when a researcher first has an idea to explore, to the moment the researcher reports the results, and when the study results translates to a meaningful output (e.g. policy change, community impact, better understanding of basic science, technology transfer).

In this context, research integrity means that during the stages of the research ecosystem researchers are encouraged to be honest, transparent, use verifiable methods in research activities, adhering to rules, regulations and guidelines, and following professional codes and norms. Furthermore, the Singapore Statement includes fourteen responsibilities which apply to researchers and institutions to conduct research ethically with integrity. In broad terms, research integrity and the responsible conduct of research include:⁵

- i) Using honest and verifiable methods in proposing, performing, and analysing research,
- ii) Reporting research results with particular attention to adherence to domain specific accepted norms and standards,
- iii) Translating output to meaningful changes (policy change, technology transfer, community impact, etc.), and
- iv) Following commonly accepted rules, regulations and professional codes.

⁵ World Conferences on Research Integrity, "Singapore Statement on Research Integrity"
<https://wcrif.org/guidance/singapore-statement>

In addition, the San Code promotes fairness throughout the research process and encourages researchers to adhere to the four principles of respect, honesty, justice and fairness, and care.⁶

The Asia-Pacific Economic Cooperation (APEC) Guiding Principles for Research Integrity acknowledge principles from other guidelines or codes such as honesty, responsibility, transparency, respect, and fairness. However, it adds further principles, for example:

- i) Rigour: this requires researchers to be careful, thorough and critical in reporting research findings, and
- ii) Diversity: encouraging researchers to be inclusive of diverse people, cultures, knowledges, perspectives and experiences.

These principles could be applied throughout the research ecosystem to ensure that research is conducted ethically and with integrity, but also to ensure that the indigenous communities and their experiences, knowledge and cultures are considered.⁷

i) [Ethical review of research involving traditional medicine](#)

Kruger et al. (2014) recommend that RECs that review research protocols involving herbal products that may have a range of impacts upon people, society or the environment should ensure that the methodological steps for ethics review are described in their applicable standard operating procedures (SOPs). The RECs should also ensure that such protocols should follow the same review processes and standards as any other type of ethics application of clinical or social science research that involves human participants. This review should occur prior to project implementation, and relevant national and international ethical guidelines should guide the review of research protocols involving herbal products in the same way as for any other human subjects (Kruger et al., 2014).

RECs should assess whether the following elements are in place in order to facilitate review of such research applications:

- i) The research team should include a team member with clinical medicine and toxicology competence,

⁶ San Code of Research Ethics. TRUST project (2017), available at <http://trust-project.eu/wp-content/uploads/2017/03/San-Code-of-RESEARCH-Ethics-Booklet-final.pdf>

⁷ APEC Research Integrity Principles Project, Report to Member Economies (2016), available at https://aimp2.apec.org/sites/PDB/Supporting%20Docs/2849/Completion%20Report/HRD%2001%202016S_APEC%20Guiding%20Principles%20for%20Research%20Integrity%20Report.pdf

- ii) That community indigenous knowledge and intellectual property rights should be recognised and preserved throughout the research process,
- iii) That international standards on ABS should be described in the application and respected in terms of the described methods of community engagement,
- iv) That there should be evidence in the ethics application that the herbal product has been subjected to rigorous toxicological testing to ensure that it is safe for human handling and/or use,
- v) That scientific evidence should be presented as part of the ethics application to support the safety profile of the herbal product (anecdotal observations, even based on indigenous knowledge, should not be regarded as sufficiently robust to be used as supporting evidence),
- vi) That plans for ABS by the community and/or by the participants should be described, particularly if there may be a commercial or financially beneficial outcome to the study such as development of a patentable product or a product that could be commercially viable,
- vii) That a data safety and monitoring plan should be in place with appropriate checks and balances for recording of data breaches,
- viii) That the process for obtaining and documenting informed consent should be clear,
- ix) That provision for confidentiality of participants and/or data should be made, and
- x) That records of preclinical (animal) data and first-phase clinical data (if applicable or inapplicable) should be maintained and available to REC members.

Furthermore, Kruger et al. (2014) recommend that collaborative partnerships with all stakeholders are considered and included as part of ethics applications. Stakeholders may include but not be limited to traditional healers, local drug regulatory authorities, local custodians of indigenous knowledge systems, and biotechnology or pharmaceutical companies. This is essential because it can help ensure the scientific and academic credibility of traditional medicine research, and also how any knowledge gained from the research may be transformed into useful, cheap and evidence-based health products (as applicable), and/or any other cultural, societal or environmental outcomes. RECs must encourage researchers to develop and maintain such partnerships.

The Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit-sharing Activities makes provision for standards in relation to traditional knowledge in the context of integrity.⁸

⁸ ABS Management Tool (2007), available at https://www.iisd.org/system/files/publications/abs_mt.pdf

The Best Practice Standard includes:

- i) That the integrity of any traditional knowledge associated with genetic resources is respected by the collector of genetic resources and by other secondary users. This therefore includes both researcher and other data partners. The collection and use of traditional knowledge should be undertaken in a considered way so as not to affect the integrity, sense and value of traditional knowledge by a range of different knowledge providers or communities, and so as to not denigrate the cultural context of indigenous knowledge systems,
- ii) That a fair and reasonable effort is made by researchers to preserve, respect and maintain traditional knowledge when it is accessed and used in ways that are appropriate for the outcomes of the study, and
- iii) That consideration is given to the fair and adequate compensation and sharing of benefits that may arise from the use of such knowledge, including a recognition of the community that holds the specific traditional knowledge associated with the genetic resource being accessed and used.

Researchers should also note that they have the responsibility to:

- i) Ensure that research activities, collection practices and engagements with different stakeholders do not violate customary law and practices, but that it works in harmony with them,
- ii) Respect the sacred values and places of traditional knowledge holders,
- iii) Ensure that any collection or use of genetic resources does not impede traditional uses of traditional knowledge, such that there are no material disadvantages associated with the collection of these resources,
- iv) Ensure that no Intellectual Property Rights (IPRs) are sought, or any form of commercialisation is undertaken in a way that affects traditional knowledge use, unless expressly permitted by the holders of the traditional knowledge, but which should be stated in a formal contractual agreement,
- v) Ensure that any information not otherwise publicly available on traditional knowledge associated with genetic resources accessed or used is not disclosed without the prior informed consent (PIC) of the traditional knowledge holders, but being aware of the limitations of communitarian decision making systems,
- vi) Negotiate and provide fair compensation for genuine grievances related to the collection of genetic resources that have damaged resources used for the livelihoods of local and indigenous communities or peoples, and

- vii) Respond to the government and stakeholder/local and indigenous community concerns related to the proposed or ongoing collection of genetic resources.

2.1.3 Benefit-sharing agreements

According to the African Union, benefit-sharing is the sharing of whatever accrues from the use of biological resources, community knowledge, technologies, innovations or practices. This definition, however, does not consider with whom or by whom these benefits should be shared. South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework (BABS) define benefit-sharing as participation in the economic, environmental, scientific, social or cultural benefits resulting or arising from access to genetic resources and associated traditional knowledge between user and provider of genetic resource and its associated traditional knowledge. This definition is more complete and for the purposes of this document it will be used to define benefit-sharing.

Different types of benefits that are negotiated with providers of biological resources or traditional knowledge vary widely according to local conditions and the nature of the organisation accessing the resource or knowledge. There is often an emphasis placed on monetary benefits, whereas non-monetary benefits may in fact deliver more durable benefits, especially in the case where capacity building or technology transfer has taken place.

The following aspects must be considered when research institutions develop benefit-sharing agreements:⁹

- i) Research institutions must comply with all the applicable laws and regulations regarding benefit-sharing in force in the provider country and/or the recipient country where data or materials are being transferred across borders,
- ii) They must consider the expressed desires and needs of the other community and its capacities when negotiating ABS provisions in a fair and constructive manner so as not to put them at a disadvantage. This includes respecting local languages and customs in negotiating practices,
- iii) They must use a comprehensive and open list to choose from possible monetary and non-monetary benefits to begin the process of negotiating benefits, to apply flexibly for the different cases and situations, and

⁹ National Health Act 2003 No. 61 of 2003 Material Transfer Agreement of Human Biological Materials, Government Gazette 20 July 2018 No. 41781, National Health Act No. 61 of 2003 section 1

- iv) They must consider short-term, medium-term and long-term benefits. The time frame of benefit-sharing should be stipulated along with alternative plans if the assumed benefits do not materialise, or if other benefits become apparent.

To protect all parties in the benefit-sharing agreement, terms and conditions must be agreed upon from the start of negotiations. These may include conditions upon which the agreement will be terminated, confidentiality of information provided, and liability for breach of the agreement.

It is also important to state who will be responsible for costs in the event of a breach of contract being settled in a court of law or through arbitration. Research institutions/researchers should agree on regular intervals to provide feedback to providers.

The information contained in the benefit-sharing agreement must be in simple, non-technical language so that local communities can understand the terms and conditions.

2.1.4 Material Transfer Agreement (MTA) and Data Transfer Agreement (DTA)

Researchers and research institutions create large amounts of research which in turn means the creation and/or collection of materials, data and intellectual property. These materials include but are not limited to biological materials and data that are collected and utilised in research and a further step in research and development (R&D) in some cases. Besides the legislation that is in place to protect such intellectual property, materials and data, ownership of and/or access to such elements, there is a need for these to be further protected when such research institutions and researchers enter into an agreement such as a MTA and/or DTA with an external party.

The guidance provided in this toolkit and in the guidelines cannot substitute the advice of a legal practitioner. Researchers and research institutions are advised to seek expert legal advice to guide the process of such agreements especially when there is intellectual property, materials and data that is involved as this may be affected the ownership, curatorship, utilisation and access to such elements. These agreements are legally binding, and rights and responsibilities are agreed when negotiating such agreements. This legal advice is vital in order for the parties to have a well-balanced and fair agreement which avoids ambiguity.

The legal expert has the expertise to know what would be in the best interests of the research, researcher and the research institution when entering into such agreements. The guidelines and

templates provided for herein is not meant to be prescriptive but rather a recommendation of where researchers and research institutions can start the process of what to consider and what elements to negotiate. Please note that in many research institutions, the research institution and not the individual researcher enters into such agreements as the research institutions have the legal standing to do so. This also depends on the research institutions policies and procedures.

Every research project is unique in its own way and the terms and nature of the agreement is negotiated on a case-by-case basis in order to be tailored to fit the needs and interests of the parties involved in that specific research project.

Material Transfer Agreements (MTAs) and Data Transferring/sharing/accessing Agreements (DTAs) are the tools that are used for such collaborations. The word 'collaboration' may also include consultancy or services provided. A MAT and DTA can allow a researcher/research institution to transfer material/s and/or allow access to data to a third party in order for them to conduct analysis of such materials and/or data. MTAs and DTAs should define what the materials and/or data are and what the material and/or data can be used for, e.g. may only be used for research purposes (in particular health research) which may be fully outlined in the annexure of the MTA or DTA. In both agreements, the parties are to engage with each other in good faith and to confirm that they will conduct themselves with the highest ethical standards and apply with all applicable legislation.

The general practice is that the research institution and/or researcher that is transferring the materials and/or data should utilise and propose its own MTA and/or DTA to the other party, which has been drafted by a legal professional, and conforming to the legislation of where the material and/or data was created applies, i.e. the jurisdiction of the source country. The parties can propose amendments accordingly and the transferring party then considers these.

[2.1.4.1 Material transfer agreements \(MTAs\)](#)

A MTA is used when human biological materials, specimens and/or samples are transferred between research (and non-research) institutions, researchers and individuals to other research (and non-research) institutions, individuals within the country or outside the country for the purpose of research. A MTA is also utilised for the transfer of materials from biobanks or from storage facilities. This agreement is to provide certainty on the ownership or custodianship of such material. In the majority of research which uses a MTA, the materials are transferred for health research purposes as

per legislation.¹⁰ A MTA may also ensure the compliance of the application of which party is to be responsible to have the necessary permits in place in order for the material, specimens and/or samples to be transferred. It will also outline any regulations that are in place which may affect the transfer and/or use of such material, specimens and/or samples.¹¹

Any materials that will be transferred to the other party will be de-identified and no link or information can be used to trace the participants who provided such biological material. The parties may agree that the material is not to be used in humans, clinical trials or for diagnostic purposes involving human subjects or for any profit-making or commercial purposes.

A primary element of a MTA is benefit-sharing, if applicable, which outlines how the parties are to discharge the obligations of such benefit-sharing, e.g. percentage of the share, who benefits, payments etc. The previous section elaborates on this notion of benefit-sharing.

2.1.4.2 Data transfer agreements (DTAs)

A DTA is used when data or portions thereof that have been collected from a research project is transferred between research (and non-research) institutions, researchers and individuals to other research (and non-research) institutions, individuals within or outside the country for the purpose of research. Data can be in any form from electronic to written form or genetic sequence data to data collected from a survey. As with MTAs, this agreement is to indicate the position on ownership or custodianship of such data. It will also outline what the data can be used for.

The data that is to be provided will be de-identified and no information will be provided that can be used to identify the participants from whom the data was collected. In some cases, the parties agree that the data is not to be used in human subjects, clinical trials or for diagnostic purposes involving human subjects or for any profit-making or commercial purposes.

Legislation around the world is being enacted and implemented for the protection of personal information which requires data to be protected as far as possible and stored in the correct manner and location. Research data management plans will be required by RECs in order to approve ethics applications. This management plan needs to consider who is the responsible party, what the lawful

¹⁰ National Health Act 2003 No. 61 of 2003 Material Transfer Agreement of Human Biological Materials, Government Gazette 20 July 2018 No. 41781, National Health Act No. 61 of 2003 section 1

¹¹ ABS Information Forum Tools & Resources - Material Transfer Agreements, available at <http://nagoyaprotocol.myspecies.info/node/3>

basis of the research is, who will be responsible for the compliance in terms of data privacy and protection laws, how data will be collected, accessed, shared and transferred.

2.1.4.3 Intellectual property (IP)

Intellectual Property (IP)¹² in the context of the Nagoya Protocol refers to any creation of the mind that is capable of being protected by law from use by any other person and includes any rights in such creation, any and/or all technical and/or commercial information, chemical structures, biological and/or chemical information, manufacturing techniques and/or designs, specifications and/or formulae, know-how, data, systems and/or processes, production methods, methodologies, trade secrets, undisclosed inventions, financial and/or marketing information, as well as registered and/or unregistered intellectual property in the form of patents and/or inventions, trademarks, designs and/or plant breeders' registrations and/or varieties (whether granted, registered and/or applied for), and/or copyright in any works including, but not limited to, literary works and/or computer software programs refers to a cluster of legally recognised rights associated with innovation and creativity – the works of the mind, as opposed to physical products, land and other tangible resources. IP clauses are found in both an MTA and DTA. These are very important clauses when a research institute and researcher and/or their legal expert is negotiating such agreements as this is the clause which determines ownership or custodianship of any and all IP which was in existence before the agreement is entered into and may be used in the current research (Background IP). Any IP created during the course and scope of the agreement (Foreground IP) is determined by these clauses. IP clauses are agreed to by the parties, which are informed by the IP legislation of which country the material and/or data was created in. Rights and obligations in terms of IP are outlined within these IP clauses and consideration is also taken on whether such rights that are pursued should be enforced or not and under what circumstances.

Research institutions and researchers also need to consider the extent of the use of the material and/or data, and how and who will benefit from any benefits that may arise if such IP is commercialised.

¹² Definitions of Intellectual Property, Background Intellectual Property and Foreground Intellectual Property have been taken from the University of the Witwatersrand, Johannesburg and Wits Commercial Enterprise Template Agreements.

2.2 Regulators (Governments/Law Makers)

2.2.1 Mutually Agreed Terms (MAT)

The Nagoya Protocol indicates that mutually agreed terms are a core element which need to have established rules.¹³ According to World Intellectual Property (WIPO),¹⁴ the terminology ‘Mutually Agreed Terms’ “refers to an agreement reached between the providers and users of genetic resources regarding the conditions for access to and utilisation of these resources, and how resulting benefits are to be shared. In practice, depending on relevant laws and regulations, mutually agreed terms on access and benefit-sharing may be negotiated between the user and various actors (governments, agencies, communities and/or other persons or entities) and set out in different types of contracts and agreements.” WIPO indicates that there are two different approaches to mutually agreed terms:

- i) Where countries delegate the negotiation to individuals or communities that are the providers of a specific genetic resource or indigenous knowledge that needs to be accessed and utilised. Therefore, the negotiating parties are to agree on the terms and conditions of the access and utilisation of the resources as well as the benefits of the use of the resources. MTAs, DTAs and collaboration agreements are the identified tools to be used in such transactions, which would be regulatory and legal compliant.
- ii) Where governments prescribe specific terms and conditions to be included in the mutually agreed terms. This would include government processes and approvals. By so doing, the specific individual or community provider will negotiate the agreement and may determine the specific types of tools to be used or provide a template to be negotiated.

2.2.2 Facilitating benefit-sharing agreement negotiations

The role of governments/law makers is to assist parties to negotiate and conclude agreements and set out how benefit-sharing agreements will be evaluated (BABS Guidelines). It is also important for governments to determine when benefit-sharing agreements are required and to establish policies, legislation and other measures that regulate bioprospecting and biotrade activities.¹⁵ Communication, education and public awareness about ABS are important aspects to an effective benefit-sharing regulatory framework. Therefore, effective implementation of Article 21 of the Nagoya Protocol plays a critical role for the overall success of benefit-sharing negotiations.

¹³ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (2011), available at <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>

¹⁴ World Intellectual Property (WIPO) and The ABS Capacity Development Initiative, A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements (2018), available at https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf

¹⁵ See <https://community.abs-sustainabledevelopment.net/knowledge/access-to-genetic-resources-and-benefit-sharing-theory-to-practice-under-the-nagoya-protocol/>

2.2.3 Conservation and sustainable use

Conservation and sustainable use are important systems that ensure or contribute to the maintenance of the diversity of genetic resources accessed during the bioprospecting process (Crouch et al., 2008). The following accepted standards based on the International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (2007)¹⁶ should be considered by governments and law makers to ensure the conservation and sustainable use of biological resources. These standards are:

- i) That the collection and/or harvesting of wild genetic or biological resources is conducted using a precautionary approach (by taking the minimum amount), at a scale and rate and in a manner that does not exceed the sustainable yield and that does not impair ecosystem structure, functions and services. This therefore requires consideration of the ecological context of any materials harvested,
- ii) That the domestication and/or the cultivation/captive breeding of genetic and biological resources are conducted in a manner that maintains the genetic variation of the population or diversity of the gene pool,
- iii) That species listed in Appendix I of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and species considered to be globally or locally threatened according to the International Union for Conservation of Nature (IUCN) Red List or equivalent categories, are not collected, except for the purpose of species conservation research. There may also be national guidelines and laws on the access and use of such materials which should be adhered to. No collection must be undertaken in legally established protected areas that prohibit collection, unless with specific permission, and
- iv) That knowledge about biodiversity that arises from access to a genetic resource is shared in a manner that supports and enhances conservation management.

2.2.4 Traditional Knowledge

The United Nations Permanent Forum on Indigenous Issues (2019) describes traditional knowledge as knowledge, innovations and practices of indigenous and local communities around the world. This knowledge is developed from experience gained over the centuries and adapted to the local culture and environment.

Article 3 of the Nagoya Protocol states that traditional knowledge will not always be accessed in combination with a genetic resource. Instead, a potential user can in certain instances only access the

¹⁶ Available at https://www.wwf.de/fileadmin/fm-wwf/Publikationen-PDF/Standard_Version1_0.pdf

traditional knowledge and not the genetic material associated with it. Government and regulators must ensure the generation, transmission, protection, maintenance and strengthening of traditional knowledge through legislative, administrative or policy measures.¹⁷

The Bonn (2005)¹⁸ guidelines on ABS and MAT refer to three aspects that should be considered when traditional knowledge is accessed:

- i) That the integrity of traditional knowledge associated with genetic resources is respected by the user,
- ii) That fair and reasonable effort is made to preserve, respect and maintain traditional knowledge associated with genetic resources when that traditional knowledge is accessed and used, and
- iii) That adequate compensation and ABS are provided, including a recognition of the community that holds the specific traditional knowledge associated with the genetic resource being accessed and used.

As the protection of traditional knowledge varies between countries, in accordance with national legislation, policy and practices, it is important to consult with the competent national authorities.

2.3 Provider/Local Communities and Holders of Traditional Knowledge

2.3.1 Prior Informed Consent (PIC)

Prior Informed Consent (PIC) is permission obtained from a provider or local community or national authority prior to the access of traditional knowledge and genetic resources by a user. Community gatekeepers need to be involved prior to any activity by the user or investors. Communities involved should be given all the relevant information in a language they can understand. The communities should also have access to a team of experts for legal or technical concerns before they can reach a decision.^{19,20}

¹⁷ IUCN Environmental Policy and Law Paper No. 83. (2012)

¹⁸ Available at <https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf>

¹⁹ Guidelines: Access and benefit sharing in research projects (2012). Available at https://www.biodiversityinternational.org/fileadmin/_migrated/uploads/tx_news/Guidelines_access_and_benefit_sharing_in_research_projects_1554.pdf

²⁰ Community Protocols Toolbox (2016). Available at https://naturaljustice.org/wp-content/uploads/2016/05/toolbox_complete.pdf

2.3.2 Mutually Agreed Terms (MATs)

2.3.2.1 General/Best Practices

Best practices encourage that Mutually Agreed Terms (MATs) should be reached and documented from the onset of a research protocol that involves genetic resources. This would include access and the use of such resources and materials. In addition, prior informed consent as described above would form part and parcel of MATs. Furthermore, MATs should clearly explain benefit-sharing in terms of benefits that may arise from the access and or use of generic resources or materials from the traditional knowledge. In essence, MATs are closely related to documenting the process use by local communities and indigenous people and other stakeholders. It is therefore important that MATs are well-documented and are available as a written agreement. In fact, MATs become a legally binding contractual agreement after all negotiations have been concluded between relevant stakeholders. This requires bona fide negotiations to ensure that the rights of community members are protected throughout the process. The MATs become the framework for the collaboration between the indigenous community (provider) and the user (researcher) and other stakeholders.

2.3.2.2 Importance and benefits of Mutual Agreed Terms, especially to indigenous community members and other stakeholders²¹

- i) MATs should be negotiated in a manner that builds confidence and a relationship of trust between owners, managers or custodians of genetic resources (indigenous communities), and the varied users of genetic resources, and that establishes the basis for a long-term, transparent and respectful relationship and communication between these different stakeholders,
- ii) MATs should be negotiated in good faith by both users and providers, respecting the terms and understanding of PIC, allowing benefits to flow within and between all stakeholders, including facilitating access, and
- iii) MATs should take into account any potential differences in capacities and needs of the different providers and user communities, including governments, indigenous and local communities, the potential holders of *ex situ* collections, as well as any potential user organisations, and to allow fair processes of negotiation and equitable outcomes in the benefits to be shared.

²¹ Available at https://www.iisd.org/system/files/publications/abs_mt.pdf

2.3.2.3 Responsibilities and Relationships

The nature of the relationship is that of collaboration and partnership. It is therefore recommended that negotiations occur in a practical manner before any legal terms and conditions are discussed. This may include language sensitivity to ensure that members of indigenous communities fully participate during the negotiation phase which will lead to MATs. At this stage, it is recommended that all parties and stakeholders seek expert advice, with experience in the relevant national legal system (or systems), which can:

- i) Confirm that the agreement properly reflects the underlying access project or research relationship, and
- ii) Clarify whether the rights and obligations are reasonable, fair and legal, and whether and how obligations under the agreement can be enforced if necessary.

It is essential that throughout the negotiation process and drawing-up on MATs that the rights of the indigenous community members who hold traditional knowledge are protected from exploitation and coercion. If required, indigenous communities as holders of traditional knowledge should have access to legal assistance to address access and use of genetic or related resources and material.²²

The Nagoya Protocol promotes equity and fairness in negotiation of MATs between providers and users of genetic resources. It is therefore required that parties shall ensure that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that MATs have been established.²³

2.3.3 Access to Traditional Knowledge

Traditional knowledge underpins indigenous peoples' identities, their cultural heritage, and livelihoods. The transmission of traditional knowledge across generations is fundamental to protecting and promoting indigenous peoples' cultures and identities and as well as the sustainability of livelihoods and appropriate economic development.²⁴

Prior informed consent is central to the sharing of traditional knowledge. Communities should develop internal processes that can be followed when traditional knowledge is accessed by users. These

²² Best Practice Standard and Handbook (2007), available at https://www.iisd.org/system/files/publications/abs_mt.pdf

²³ Nagoya Protocol on Access and Benefit-sharing (2011), available at <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>

²⁴ Knowing our Lands and Resources: Indigenous and Local Knowledge of Biodiversity and Ecosystem Services in Africa (2017), Available at http://www.climatefrontlines.org/sites/default/files/ipbes/IPBES_Africa_2016_V25_FINAL.pdf

mechanisms should enable communities to make informed decisions about how traditional knowledge is shared and what benefits will be negotiated for access to traditional knowledge. Community leaders must also educate members on how to protect traditional knowledge, and what procedures to follow when they are approached by researchers or companies.

Communities can consider the following aspects when developing processes for the maintenance and management of its traditional knowledge:

- i) A community representative or a community council should be elected to ensure that the interest of the local community is protected when its traditional knowledge is accessed,
- ii) This council should train the community of the value of traditional knowledge and that it should not be shared without the permission of the whole community, and
- iii) Processes should be developed to record (on paper or digitally) traditional knowledge for the benefit of future generations of the community.

SECTION 3: USEFUL TEMPLATES

Any templates that are provided herein serve as a guideline only. They are not prescriptive or mandatory in any way.

3.1 Types of ABS Agreements

The types of ABS Agreements that one can utilise are as follows:

- i) Material Transfer Agreements,
- ii) Data Transfer Agreements,
- iii) Access and Benefit-Sharing Agreements,
- iv) Collaboration Agreements,
- v) Project Agreements,
- vi) Licensing Agreements, and
- vii) Community Research Agreements.

SAMPLE AGREEMENTS	LINK
Sample ABS agreements	https://drive.google.com/drive/folders/1pAwRS2-QSsz2RzQi77VdXzKIMi2AD7GTA?usp=sharing

3.2 Factors Affecting the Content of ABS Agreements

The following are factors that may be considered by a researcher, research institution etc. when considering the content of an ABS Agreement:²⁵

- i) The type of Agreement that is required,
- ii) The nature of the relationship of the contracting parties,
- iii) Who are the parties to the specific Agreement (do they have authority to be party to such an agreement),
- iv) Whether there are any Mutually Agreed Terms,
- v) The roles and responsibilities (joint obligations) of the parties to the Agreement. This will include acknowledgements by the recipient party,
- vi) Are there any materials, data, scientific information and/or indigenous knowledge that will be collected, accessed and/or transferred and to whom,
- vii) The use and purpose of the materials, data, scientific information and/or indigenous knowledge,
- viii) The limitation or restrictions of transfer by any of the Parties to any third party that requires the written consent of the other contracting party to this Agreement,
- ix) Benefit-Sharing—who will benefit, how will payment be made, how much will be paid, including benefit-sharing between the recipient and the provider, what will the benefit be and over what duration etc.,
- x) Intellectual Property Rights as discussed above,
- xi) Confidentiality—what the parties must keep confidential and to establish what may be made public,
- xii) Informed Consent,
- xiii) Regulatory Requirements—who will apply for the necessary permits, licences for example,
- xiv) Publication and Publicity which includes the research publications and the publications of results,
- xv) Duration of the Agreement,
- xvi) Breach Termination of the Agreement,
- xvii) Force Majeure,
- xviii) Dispute Resolution,

²⁵ Access and Benefit Sharing Agreements: Resources and Background Materials (2018), available at <https://www.voices4biojustice.org/wp-content/uploads/2017/12/ABS-Agreements-Packet-LOGO-sml.pdf>

- xix) Limitation of Liability, and
- xx) Applicable Jurisdiction and Laws.

3.3 Material Transfer Agreements

- i) https://www.gov.za/sites/default/files/gcis_document/201808/41781gon719.pdf
- ii) <http://nagoyaprotocol.myspecies.info/node/3>
- iii) <https://www.voices4biojustice.org/wp-content/uploads/2017/12/ABS-Agreements-Packet-LOGO-sml.pdf>

SAMPLE TEMPLATES	LINK
Sample MTAs	https://drive.google.com/drive/folders/1zndsAQNjzIK0uB-ZppzISJH-ZZuSivhG?usp=sharing

3.4 Data Sharing Agreements

- i) <https://www.voices4biojustice.org/wp-content/uploads/2017/12/ABS-Agreements-Packet-LOGO-sml.pdf>

SAMPLE TEMPLATES	LINK
Sample DTAs	https://drive.google.com/drive/folders/1CwPYpTd2Flm5zwjQOAngm1VO8ZWFH7FL?usp=sharing

3.5 Non-disclosure Agreements

SAMPLE TEMPLATES	LINK
Sample NDAs	https://drive.google.com/drive/folders/1jpSciB3wfMWANtzKJ4IDzy6IQZw3yq9n?usp=sharing

3.6 Prior Informed Consent Content Development

In countries where the regulatory framework regarding ABS exists, the prior informed consent (PIC) process goes hand in hand with material transfer agreements (MAT). In countries where these processes are not well developed, a task team needs to be appointed to facilitate the process. The team of experts can include:

- i) Community leaders (also named local gatekeepers). These will be representatives of the community and could include local leaders, traditional healers or senior figures in the local community or representatives of the host country,
- ii) Investigator team (principal investigator or sponsor), and
- iii) Independent legal representatives from both parties.

The process needs to include several meetings with all the representatives that will set out the project in a language that is understood by the community, or with the use of a language interpreter. Sufficient time should be provided to the community to consult with legal and/or technical experts before this process can be concluded. In most cases, mutual agreements result in the drafting of a memorandum of understanding between all the parties. For the process to be duly completed, formal signed documents need to complete both the PIC and MAT process before the research may commence.²⁶

3.7 Research Ethics Checklist

Several useful checklists have been obtained as examples of 'best practice' checklists for reviewers and researchers and will be shared as annexures.

SAMPLE CHECKLISTS	LINK
New research application (Pointers for reviewers)	https://drive.google.com/file/d/1hPwOP5iNgUXLYuEX7lkz8CMWqYcDP64-/view?usp=sharing
Biosafety review checklist	https://drive.google.com/file/d/1B2PvDeeeGHAHvgWJmKvPj73IWF7YX-cR/view?usp=sharing
Animal ethics reviewer checklist	https://drive.google.com/file/d/1BBQH8FX0YJYrrnpi7mMhTs4MdTyp-/view?usp=sharing
Informed consent review checklist	https://drive.google.com/file/d/1-oaX0KYFeTSnYVDh3DiglFMfnXji1woj/view?usp=sharing
Risk assessment tool for researchers	https://drive.google.com/file/d/1iREV8tCLtoDNm2pMXzANswvAsZ-ujcit/view?usp=sharing
Sample templates for informed consent	https://drive.google.com/drive/folders/1GmJtg1u-cXAWsDyumYDB2fpJdC6E1Kg?usp=sharing

²⁶ Kenya's access and benefit sharing toolkit for genetic resources and associated traditional knowledge (2014), available at <https://absch.cbd.int/database/record?documentID=238496>

3.8 Useful Links and Other Resources

SITE / DOCUMENT	LINK
Convention on Biological Diversity	https://www.cbd.int/abs/
Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity	www.cbd.int/abs/text/
ABSCH -The Access and Benefit-Sharing Clearing House	https://absch.cbd.int/
ABS Information Forum	http://nagoyaprotocol.myspecies.info/
Agreement on Access and Benefit-Sharing for Non-Commercial Research	https://www.cbd.int/abs/doc/model-clauses/noncommresearch-abs-agreement.pdf
Access and Benefit-Sharing Agreements: Resources and Background Materials	https://www.voices4biojustice.org/wp-content/uploads/2017/12/ABS-Agreements-Packet-LOGO-sml.pdf
African Union Practical Guidelines for Coordinated Implementation of the Nagoya Protocol in Africa	http://www.abs-initiative.info/fileadmin/media/Knowledge_Center/Publications/African_Union_Guidelines/AU_Practical_Guidelines_On_ABS_-_20150215.pdf
National Health Act 2003 No. 61 of 2003 Material Transfer Agreement of Human Biological Materials, Government Gazette 20 July 2018 No. 41781, clause 3.4	https://www.gov.za/sites/default/files/gcis_document/201808/41781gon719.pdf
ABS Information Forum “Tools & Resources - Material Transfer Agreements”	http://nagoyaprotocol.myspecies.info/node/3
A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements	https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf

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